DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS–5535–F]

RIN 0938–AU51

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 describes a new mandatory alternative payment model, the Increasing Organ Transplant Access Model (IOTA Model), that will test whether performance-based upside risk payments or downside risk payments paid to or owed by participating kidney transplant hospitals increase access to kidney transplants for patients with end-stage renal disease (ESRD) while preserving or enhancing the quality of care and reducing Medicare expenditures. This final rule also adopts standard provisions that will apply to the Radiation Oncology Model, the End-Stage Renal Disease (ESRD) Treatment Choices Model, and mandatory Innovation Center models, including the IOTA Model, whose first performance period begins on or after January 1, 2025. The finalized standard provisions relate to beneficiary protections; cooperation in model evaluation and monitoring; audits and records retention; rights in data and intellectual property; monitoring and compliance; remedial action; model termination by CMS; limitations on review; miscellaneous provisions on bankruptcy and other notifications; and the reconsideration review process.

DATES: These regulations are effective January 3, 2025.

FOR FURTHER INFORMATION CONTACT:

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

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

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

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

CMMI-StandardProvisions@cms.hhs.gov for questions related to the Standard Provisions for Innovation Center Models.

SUPPLEMENTARY INFORMATION:

Current Procedural Terminology (CPT) Copyright Notice

Throughout this final rule, we use CPT® codes and descriptions to refer to a variety of services. We note that CPT® codes and descriptions are copyright 2020 American Medical Association (AMA). All Rights Reserved. CPT® is a registered trademark of the American Medical Association. Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

Section 1115A of the Social Security Act (the Act) gives the Secretary of the Department of Health and Human Services the authority to test innovative payment and service delivery models to reduce program expenditures in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of care furnished to individuals covered by such programs. Specifically, section 1115A(b)(2)(a) of the Act states that ''the Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title.'' [1] This final rule describes a new mandatory Medicare payment model to be tested under section 1115A of the Act—the Increasing Organ Transplant Access Model (IOTA Model)—which will begin on July 1, 2025, and end on June 30, 2031. In this final rule, we address payment policies, participation requirements, and other provisions to test the IOTA Model. We will test whether performance-based incentives (including both upside and downside risk payments) for participating kidney transplant hospitals can increase the number of functioning kidney transplants (including both living donor and deceased donor transplants) furnished to end stage renal disease (ESRD) patients, encourage investments in care processes and patterns with respect to patients who need kidney transplants, encourage investments in value-based care and improvement activities, and promote greater accountability by participating kidney transplant hospitals by tying payments to the value of the care provided. The IOTA Model is also intended to advance health equity by improving equitable access to the transplantation ecosystem for all patients, such as rural and underserved populations, through design features such as voluntary health equity plans to address health outcome disparities.

This final rule also includes standard provisions that will apply to the RO Model, the ETC model, and all mandatory Innovation Center models whose first performance periods begin on or after January 1, 2025. The standard provisions address beneficiary protections; cooperation in model evaluation and monitoring; audits and record retention; rights in data and intellectual property; monitoring and compliance; remedial action; model termination by CMS; limitations on review; miscellaneous provisions on bankruptcy and other notifications; and the reconsideration review process.

As we stated in the notice of proposed rulemaking, the IOTA Model will test ways to reduce Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries. We are finalizing several, but not all, of the provisions discussed in the proposed rule, and we intend to address certain other provisions discussed in the proposed rule in future rulemaking. We also note that some of the public comments were outside of the scope of the 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 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 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

[1] U.S. Congress. (1940) United States Code: Social Security Act, 42 U.S.C. 1315a(b)(2)(a).

circumstances. Through this 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.

B. Summary of the Provisions

1. Standard Provisions for Innovation Center Models

The standard provisions for Innovation Center models will be applicable to the RO Model, the ETC Model, and all mandatory Innovation Center models whose first performance periods begin on or after January 1, 2025.

We are codifying these standard provisions to increase transparency, efficiency, and clarity in the operation and governance of mandatory Innovation Center models, and to avoid the need to restate the provisions in each model's governing documentation. The standard provisions include terms that have been repeatedly memorialized, with minimal variation, in existing models' governing documentation. The standard provisions are not intended to encompass all of the terms and conditions that will apply to each mandatory Innovation Center model, as each model includes unique design features and implementation plans that may require additional, more tailored provisions, including with respect to payment methodology, care delivery and quality measurement, that will continue to be included in each model's governing documentation. We note that while we are not finalizing our proposal to apply the standard provisions to voluntary Innovation Center models, we expect to utilize the provisions in voluntary models and will incorporate them by reference into the models' governing documentation as appropriate based on the model's design. Model-specific provisions applicable to the IOTA Model are described in section III of this final rule.

2. Model Overview—Proposed Increasing Organ Transplant Access Model

a. Proposed IOTA Model Overview

End-Stage Renal Disease (ESRD) is a medical condition in which a person's kidneys cease functioning on a permanent basis, leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life.[2] The best treatment for most patients with kidney failure is kidney transplantation. Nearly 808,000 people in the United States are living with ESRD, with about 69 percent on dialysis and 31 percent with a kidney transplant.[3] Relative to dialysis, a kidney transplant can improve survival, reduce avoidable health care utilization and hospital acquired conditions, improve quality of life, and lower Medicare expenditures.[4] [5] However, despite these benefits of kidney transplantation, evidence shows low rates of ESRD patients placed on kidney transplant hospitals' waitlists, a decline in living donors over the past 20 years, and underutilization of available donor kidneys, coupled with increasing rates of donor kidney discards, and wide variation in kidney offer acceptance rates and donor kidney discards by region and across kidney transplant hospitals.[6] [7] Further, there are substantial disparities in both deceased and living donor transplantation rates among structurally disadvantaged populations. Strengthening and improving the performance of the organ transplantation system is a priority for the Department of Health and Human Services (HHS).[8] Consistent with this priority, and through joint efforts with HHS' Health Resources and Services Administration (HRSA), the IOTA Model will aim to reduce Medicare expenditures and improve quality performance and equity in kidney transplantation by creating performance-based incentive payments for participating kidney transplant hospitals tied to kidney transplant] access and quality of care for ESRD patients on the hospitals' waitlists.

The IOTA Model will be a mandatory model that will begin on July 1, 2025, and end on June 30, 2031, resulting in a 6-year model performance period comprised of 6 individual performance years (''PYs''). The IOTA Model will test whether performance-based incentives paid to, or owed by, participating kidney transplant hospitals can increase access to kidney transplants for patients with ESRD, while preserving or enhancing quality of care and reducing Medicare expenditures. CMS will select kidney transplant hospitals to participate in the IOTA Model through the methodology proposed in section III.C.3.d of this final rule. As this will be a mandatory model, the selected kidney transplant hospitals will be required to participate. CMS will measure and assess the participating kidney transplant hospitals' performance during each PY across three performance domains: achievement, efficiency, and quality.

The achievement domain will assess each participating kidney transplant hospital on the overall number of kidney transplants performed during a PY, relative to a participant-specific target. The efficiency domain will assess the kidney organ offer acceptance rate ratios of each participating kidney transplant hospital relative to a national ranking or the participating kidney transplant hospital's past organ offer acceptance rate ratio. The quality domain will assess the quality of care provided by the participating kidney transplant hospitals via a composite graft survival ratio. Each participating kidney transplant hospital's performance score across these three domains will determine its final performance score and corresponding amount for the upside risk payment that CMS would pay to the participating kidney transplant hospital, or the downside risk payment that would be owed by the participating kidney transplant hospital to CMS. The upside risk payment will be a lump sum payment paid by CMS after the end of a PY to a participating kidney transplant hospital 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 participating kidney transplant hospital with a final performance score of 40 or lower. There is no downside risk payment for PY 1 of the model.

[2] End-Stage Renal Disease (ESRD) | CMS. (n.d.). *https://www.cms.gov/medicare/coordination-benefits-recovery/overview/end-stage-renal-disease-esrd.*

[3] United States Renal Data System. 2022 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2022.

[4] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S., & Gill, J. (2011). Systematic Review: Kidney Transplantation Compared With Dialysis in Clinically Relevant Outcomes. *American Journal of Transplantation, 11*(10), 2093–2109. *https://doi.org/10.1111/j.1600-6143.2011.03686.x.*

[5] Cheng, X.S., Han, J., Braggs-Gresham, J.L., Held, P.J., Busque, S., Roberts, J.P., Tan, J.C., Scandling, J.D., Chertow, G.M., & Dor, A. (2022). Trends in Cost Attributable to Kidney Transplantation Evaluation and Waitlist Management in the United States, 2012–2017. *JAMA network open, 5*(3), e221847. *https://doi:10.1001/jamanetworkopen.2022.1847.*

[6] Al Ammary, F., Bowring, M.G., Massie, A.B., Yu, S., Waldram, M.M., Garonzik-Wang, J., Thomas, A.G., Holscher, C.M., Qadi, M.A., Henderson, M.L., Wiseman, A.C., Gralla, J., Brennan, D.C., Segev, D.L., & Muzaale, A.D. (2019). The changing landscape of live kidney donation in the United States from 2005 to 2017. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 19*(9), 2614–2621. *https://doi.org/10.1111/ajt.15368.*

[7] Mohan, S., Yu, M., King, K.L., & Husain, S.A. (2023). Increasing Discards as an Unintended Consequence of Recent Changes in United States Kidney Allocation Policy. *Kidney International Reports, 8*(5), 1109–1111.

[8] *https://doi.org/10.1016/j.ekir.2023.02.1081.*

b. Model Scope

Participation in the IOTA Model will be mandatory for approximately 50 percent of all eligible kidney transplant hospitals in the United States. We anticipate that a total of approximately 90 kidney transplant hospitals will be selected to participate in the IOTA Model. Additionally, we note that we intend to publicly post information regarding the selection process and how it resulted in the list of DSAs and kidney transplant hospitals selected to participate in the model. As discussed in section III.C.3.b. of this final rule, we believe that mandatory participation is necessary to minimize the potential for selection bias and to ensure a representative sample size nationally, thereby guaranteeing that there will be adequate data to evaluate the model test.

Eligible kidney transplant hospitals will be those that: (1) performed at least eleven kidney transplants for patients 18 years of age or older annually regardless of payer type during the three-year period ending 12 months before the model's start date; and (2) are non-pediatric transplant facilities that furnished more than 50 percent of the hospital's annual kidney transplants to patients 18 years of age or older during that same period. CMS will select the kidney transplant hospitals that will be required to participate in the IOTA Model from the group of eligible kidney transplant hospitals using a stratified random sampling of donation service areas (''DSAs'') to ensure that there is a fair selection process and representative group of participating kidney transplant hospitals. For the purposes of this final rule, a DSA has the same meaning given to that term at 42 CFR 486.302.

c. Performance Assessment

CMS will assess each participating kidney transplant hospital's performance across three performance domains during each PY of the model, with a maximum possible final performance score of 100 points. The three performance domains will include: (1) an achievement domain worth up to 60 points, (2) an efficiency domain worth up to 20 points, and (3) a quality domain worth up to 20 points.

The achievement domain will assess the number of kidney transplants performed by each IOTA participant for attributed patients, with performance on this domain worth up to 60 points. The final performance score will be heavily weighted on the achievement domain to align with the IOTA Model's goal to increase access to kidney transplants to improve the quality of care and reduce Medicare expenditures. The IOTA Model theorizes that improvement activities, including those aimed at reducing unnecessary deceased donor discards and increasing living donors, may help increase access to kidney transplants.

CMS will set a target number of kidney transplants for each IOTA participant for each PY to measure the IOTA participant's performance in the achievement domain), as described in section III.C.5.c of the final rule. Each IOTA participant's transplant target for a given PY will be based on the IOTA participant's historical volume of deceased and living donor transplants furnished to attributed patients in the relevant baseline years, adjusted by the national trend rate in the number of kidney transplants performed. Section III.C.5.c. of this final rule describes the variation in the number of kidney transplants performed across kidney transplant hospitals, which would make it challenging to set transplant targets on a regional or national basis. The IOTA Model will therefore set a transplant target that is specific to each IOTA participant to address this concern, while still accounting for the national trend rate in the number of kidney transplants performed. It is expected that IOTA participants' transplant targets may change from PY to PY due to this calculation methodology.

The efficiency domain will assess the kidney organ offer acceptance rate ratio for each IOTA participant. The kidney organ offer acceptance rate ratio measures the number of kidneys an IOTA participant accepts for transplant over the expected value, based on variables such as kidney quality. CMS will assess the kidney organ offer acceptance rate ratio relative to either the kidney organ offer acceptance rate ratio across all kidney transplant hospitals or the IOTA participant's own past kidney organ offer acceptance rate ratio, with CMS using whichever method results in the IOTA participant receiving the most points, with performance on the efficiency domain being worth up to 20 points.

Finally, the quality domain will assess IOTA participants' performance on a composite graft survival ratio measuring post-transplant outcomes—relative to the composite graft survival ratio across all kidney transplant hospitals, with performance on this domain being worth up to 20 points.

Each IOTA participant's final performance score will be the sum of the points earned for each domain: achievement, efficiency, and quality. The final performance score in a PY will determine whether the IOTA participant will be eligible to receive an upside risk payment from CMS, fall into the neutral zone where no upside or downside risk payment would apply, or owe a downside risk payment to CMS for the PY as described in section III.C.6 of this final rule.

d. Performance-Based Upside Risk Payment and Downside Risk Payment Formula

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 of 60 and above, CMS will apply the formula for the upside risk payment, which will be equal to the IOTA participant's final performance score minus 60, then divided by 40, then multiplied by $15,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to attributed patients with Medicare Fee-for-Service (FFS) as their primary or secondary payer during the PY. Final performance scores below 60 in PY 1 and final performance scores of 41 to 59 (inclusive) in PYs 2–6 will fall in the neutral zone where there will be no payment owed to the IOTA participant or CMS.

We will phase-in the downside risk payment beginning in PY2. We explain in section III.C.5.b of this final rule that new entrants to value-based payment models may need a ramp-up period before they are able to accept downside risk. Thus, the IOTA Model utilizes an upside risk-only approach for PY 1 as an incentive in each of the three performance domains. This will give IOTA participants time to consider, invest in, and implement value-based care and quality improvement initiatives before downside risk payments begin. Beginning in PY 2, for a final performance score of 40 and below, CMS will apply the formula for the downside risk payment, which will be equal to 40 minus the IOTA participant's final performance score, then divided by 40, then multiplied by $2,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to attributed patients with Medicare FFS as their primary or secondary payer during the PY.

CMS will pay the upside risk payment in a lump sum to the IOTA participant after the PY. The IOTA participant will pay the downside risk payment to CMS in a lump sum after the PY.

e. Data Sharing

CMS will collect certain quality, clinical, and administrative data from IOTA participants for model monitoring and evaluation activities under the authority in 42 CFR 403.1110(b). We will also share certain data with IOTA participants upon request as described in section III.C.3.a. of this final rule and as permitted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and other applicable law. We will offer each IOTA participant the opportunity to request certain beneficiary-identifiable data for their attributed Medicare beneficiaries for treatment, case management, care coordination, quality improvement activities, and population-based activities relating to improving health or reducing health care costs, as permitted by 45 CFR 164.506(c). The data uses and sharing will be allowed only to the extent permitted by the HIPAA Privacy Rule and other applicable law and CMS policies. We will also share certain aggregate, de-identified data with IOTA participants.

f. Other Requirements

There are several other model requirements for selected transplant hospitals, including transparency requirements and public reporting requirements. IOTA participants may also submit a voluntary health equity plan during the model, as described in section III.C.8. of this rule.

(1) Transparency Requirements

Patients are often unsure whether they qualify for a kidney transplant at a given kidney transplant hospital. IOTA participants will be required to publish, on a public facing website, the criteria they use when determining whether or not to add a patient to the kidney transplant waitlist.

(2) Health Equity Requirements

An IOTA participant may submit a health equity plan (''HEP'') to CMS. The submission of HEPs will be voluntary for IOTA participants for the duration of the model. The HEP will identify health disparities within the IOTA participant's population of attributed patients and outline a course of action to address them.

g. Medicare Payment Waivers and Additional Flexibilities

We believe it is necessary to waive certain requirements of title XVIII of the Act solely for purposes of carrying out the testing of the IOTA Model under section 1115A of the Act. We will issue these waivers using our waiver authority under section 1115A(d)(1) of the Act, which states that the Secretary may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of carrying out this section with respect to testing models described in section 1115A(b) of the Act. Each of the waivers is discussed in detail in section III.C.11.i. of this final rule.

h. Overlaps With Other Innovation Center Models and CMS Programs

We expect that there could be situations where a Medicare beneficiary attributed to an IOTA participant is also assigned, aligned, or attributed to another Innovation Center model or CMS program. Overlap could also occur among providers and suppliers at the individual or organization level, such as where an IOTA participant or one of their providers participates in multiple Innovation Center models. We believe that the IOTA Model will be compatible with existing models and programs that provide opportunities to improve care and reduce spending. The IOTA Model will not be replacing any covered services or changing the payments that participating hospitals receive through the inpatient prospective payment system (IPPS) or outpatient prospective payment system (OPPS). Rather, the IOTA Model implements performance-based payments separate from what participants will be paid by CMS for furnishing kidney transplants to Medicare beneficiaries. Additionally, we will work to resolve any potential overlaps between the IOTA Model and other Innovation Center models or CMS programs that could result in duplicative payments for services, or duplicative counting of savings or other reductions in expenditures. Therefore, we are allowing overlaps between the IOTA Model and other Innovation Center models and CMS programs.

i. Monitoring

We will closely monitor the implementation and outcomes of the IOTA Model throughout its duration consistent with the monitoring requirements in the Standard Provisions for Innovation Center models in section II of this final rule and the requirements in section III.C.13. of this final rule. The purpose of this monitoring will be to ensure that the IOTA Model is implemented safely and appropriately, that the quality and experience of care for beneficiaries is not harmed, and that adequate patient and program integrity safeguards are in place.

j. Beneficiary Protections

As mentioned in section III.C.10. of this final rule, CMS will not allow beneficiaries or patients to opt out of attribution to an IOTA participant; however, the IOTA Model will not restrict a beneficiary's freedom to choose another kidney transplant hospital or any other provider or supplier for healthcare services, and IOTA participants will be subject to the Standard Provisions for Innovation Center Models outlined in section II of this final rule protecting Medicare beneficiary freedom of choice and access to medically necessary services. We also require that IOTA participants notify Medicare beneficiaries of the IOTA participant's participation in the IOTA Model by, at a minimum, prominently displaying informational materials in offices or facilities where beneficiaries receive care.

C. 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. Based on quantitative and qualitative analyses, there is reasonable evidence that the savings to Medicare resulting from an incremental growth in transplantation as a result of the IOTA Model will potentially exceed the payments projected under the model's incentive structure.

II. Standard Provisions for Innovation Center Models

A. Introduction

Section 1115A of the Act authorizes the Center for Medicare and Medicaid Innovation (the ''Innovation Center'') to ''test innovative payment and service delivery models to reduce program expenditures under the applicable titles [Medicare, Medicaid, and CHIP] while preserving or enhancing the quality of care furnished to individuals under such titles . . . In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services . . .'' 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.

On September 29, 2020, we published in the **Federal Register** a final rule titled ''Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures'' (85 FR 61114) (hereinafter the ''Specialty Care Models final rule''), in which we adopted General Provisions Related to Innovation Center models at 42 CFR part 512 subpart A that apply to the End-Stage Renal Disease Treatment Choices (ETC) Model and the Radiation Oncology (RO) Model.[9] The Specialty Care Models final rule codified general provisions regarding beneficiary protections, cooperation in model evaluation and monitoring, audits and record retention, rights in data and intellectual property, monitoring and compliance, remedial action, model termination by CMS, limitations on review, and bankruptcy and other notifications. These general provisions were adopted only for the ETC and RO Models (and, in practice, applied only to the ETC Model). However, in the notice of proposed rulemaking, we explained that we now believe the general provisions should apply to Innovation Center models more broadly. As we noted, the Innovation Center models share numerous similar provisions, and we explained that we believed codifying the general provisions in regulation to expand their applicability across models, except where otherwise explicitly specified in a model's governing documentation, would promote transparency, efficiency, clarity, and ensure consistency across models to the extent appropriate, while avoiding the need to restate the provisions in each model's governing documentation.

We also proposed a new provision pertaining to the reconsideration review process that would apply to Innovation Center models that waive the appeals processes provided under section 1869 of the Act.

B. General Provisions Codified in the Code of Federal Regulations That Would Apply to Innovation Center Models

Each Innovation Center model features many unique aspects that must be memorialized in its governing documentation, but each model also includes certain provisions that are common to most or all models. We explained that we believe codifying these common provisions would facilitate their uniform application across models (except where the governing documentation for a particular model dictates otherwise) and promote program efficiency and consistency that would benefit CMS' program administration and model participants.

As such, we proposed to expand the applicability of the 42 CFR part 512 subpart A ''General Provisions Related to Innovation Center Models'' to all Innovation Center models whose first performance periods begin on or after January 1, 2025, unless otherwise specified in the models' governing documentation, and also to any Innovation Center models whose first performance periods begin prior to January 1, 2025 if incorporated by reference into the models' governing documentation. To accomplish this, we proposed that the provisions codified at 42 CFR part 512 subpart A for the ETC and RO Models, including those with respect to definitions, beneficiary protections, cooperation in model evaluation and monitoring, audits and record retention, rights in data and intellectual property, monitoring and compliance, remedial action, Innovation Center model termination by CMS, and limitations on review, would be designated as the newly defined ''standard provisions for Innovation Center models'' and would apply to all Innovation Center models as described previously. We proposed specific revisions that would be necessary to expand the scope of several of the current general provisions, but otherwise proposed that the general provisions (which would be referred to as the ''standard provisions for Innovation Center models'') would not change. In particular, we proposed that the substance of the following provisions would not change, except that they would apply to all Innovation Center Models as opposed to just the ETC and RO Models: § 512.120 Beneficiary protections; § 512.130 Cooperation in model evaluation and monitoring; § 512.135 Audits and record retention; § 512.140 Rights in data and intellectual property: § 512.150 Monitoring and compliance; § 512.160 Remedial action; § 512.165 Innovation center model termination by CMS; § 512.170 Limitations on review; and § 512.180 Miscellaneous provisions on bankruptcy and other notifications.

C. Revisions to the Titles, Basis and Scope Provision, and Effective Date

We proposed to amend the title of part 512 to read ''Standard Provisions for Innovation Center Models and Specific Provisions for the Radiation Oncology Model and the End Stage Renal Disease Model'' so that it more

[9] In the autumn of 2020, due to the Secretary of Health and Human Services' Determination that a Public Health Emergency Exists for the Coronavirus disease 2019 (COVID–19) (*https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx*), CMS revised the RO Model's performance period to begin on July 1, 2021, and to end on December 31, 2025, in the CY 2021 Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs final rule with comment period (85 FR 85866). Section 133 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260) (hereinafter referred to as ''CAA, 2021''), enacted on December 27, 2020, included a provision that prohibited implementation of the RO Model before January 1, 2022. This congressional action superseded the July 1, 2021, start date that we had established in the CY 2021 OPPS/ASC IFC. To align the RO Model regulations with the requirements of the CAA, 2021, we proposed to modify the definition of ''model performance period'' in 42 CFR 512.205 to provide for a 5-year model performance period starting on January 1, 2022, unless the RO Model was prohibited by law from starting on January 1, 2022, in which case the model performance period would begin on the earliest date permitted by law that is January 1, April 1, or July 1. We also proposed other modifications both related and unrelated to the timing of the RO Model in the proposed rule that appeared in the August 4, 2021, **Federal Register** titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals'' (86 FR 42018). These provisions were finalized in a final rule with comment period titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model'' that appeared in the November 16, 2021 **Federal Register** (86 FR 63458) (hereinafter referred to as the ''CY 2022 OPPS/ASC FC'').

On December 10, 2021, the Protecting Medicare and American Farmers from Sequester Cuts Act (Pub. L. 117–71) was enacted, which included a provision that prohibits implementation of the RO Model prior to January 1, 2023. The CY 2022 OPPS/ASC final rule with comment period specified that if the RO Model was prohibited by law from beginning on January 1, 2022, the model performance period would begin on the earliest date permitted by law that is January 1, April 1, or July 1. As a result, under the current definition for model performance period at § 512.205, the RO Model would have started on January 1, 2023, because that date is the earliest date permitted by law. However, given the multiple delays to date, and because both CMS and RO participants must invest operational resources in preparation for implementation of the RO Model, we have considered how best to proceed under these circumstances. In a final rule titled ''Radiation Oncology (RO) Model,'' which appeared in the **Federal Register** on August 29, 2022 (87 FR 52698), we delayed the start date of the RO Model to a date to be determined through future rulemaking, and modified the definition of the model performance period at § 512.205 to provide that the start and end dates of the model performance period for the RO Model would be established in future rulemaking. We have not undertaken rulemaking to determine the start date for the RO Model and, thus, the model is not active at this time.

closely aligns with the other changes we proposed and to ensure that the title indicates that part 512 includes both standard provisions for Innovation Center models and specific provisions for the RO and ETC Models. We also proposed to amend the title of subpart A to read ''Standard Provisions for Innovation Center Models'' to use the term we proposed to define the provisions codified at 42 CFR part 512 subpart A.

Additionally, we proposed to amend § 512.100(a) and (b) so that the standard provisions would take effect on January 1, 2025, and would apply to each Innovation Center model where that model's first performance period begins on or after January 1, 2025, unless the model's governing documentation indicates otherwise, as well as any Innovation Center model that begins testing its first performance period prior to January 1, 2025, if the model's governing documentation incorporates the provisions by reference in whole or in part. We proposed to determine on a case-by-case basis, based on each model's unique features and design, whether the standard provisions would apply to a particular model, or whether we would specify alternate terms in the model's governing documentation.

We noted in the proposed rule that these standard provisions are necessary for the testing of the IOTA Model. As such, as an alternative to the previous proposal, we proposed making these standard provisions for Innovation Center models applicable to, and effective for, the IOTA Model beginning on January 1, 2025, absent extending the standard provisions to all Innovation Center models. Under such an alternative, the general provisions in the Specialty Care Models final rule would also still be applicable to the ETC Model and the RO Model.

We specified in the proposed rule that these proposed standard provisions would not, except as specifically noted in section II of the proposed rule, affect the applicability of other provisions affecting providers and suppliers under Medicare fee-for-service (FFS). We invited public comment on these proposed changes.

Comment: We received a comment that emphasized that the proposed standard provisions should not affect the applicability of other provisions affecting providers and suppliers under Medicare fee-for-service. The commenter believed that standardization of provisions across models would decrease administrative burden for providers and simplify understanding of complex models.

Response: We thank the commenter for their comment. We agree. We are finalizing the proposed regulation text at § 512.100(b)(3) to provide that, except as specifically noted in subpart A of Part 512, the standard provisions will not affect the applicability of other provisions affecting providers and suppliers under Medicare fee-for-service, including provisions regarding payment, coverage, and program integrity. We agree with the commenter that the standardization of provisions across models will decrease administrative burden and simplify understanding of our Innovation Center models.

After consideration of the public comment we received, we are finalizing the proposed revisions to the titles for 42 CFR part 512 and for subpart A as described later in this section. Further, we are finalizing the proposed revisions to the basis and scope provision at 42 CFR 512.100 with modification to apply the standard provisions to mandatory Innovation Center models that begin their performance periods on or after January 1, 2025, rather than to both mandatory and voluntary Innovation Center models. After further consideration, we do not believe it is necessary to adopt the standard provisions for voluntary models because we can include those provisions, or other provisions, if necessary, in the models' governing documentation. We also are not including in the final regulation text the reference to applying the standard provisions ''unless otherwise specified in the Innovation Center model's governing documentation'' at proposed § 512.100(b)(ii) because we are able to include the standard provisions, or other provisions as appropriate, in voluntary Innovation Center model participation agreements. We anticipate utilizing the standard provisions in most voluntary Innovation Center model participation agreements and will reference them or incorporate them by reference as appropriate.

We also are not codifying the proposed regulation text at § 512.100(b)(i), which provided that the standard provisions would apply to each Innovation Center model that began its first performance period before January 1, 2025, if incorporated by reference, in whole or in part, into the Innovation Center model's governing documentation. If we believe it is appropriate to apply the standard provisions, in whole or in part, to an Innovation Center model for which the first performance period began before January 1, 2025, we will amend the model's governing documentation as appropriate, including through notice and comment rulemaking if necessary. We are finalizing that the standard provisions will apply to the RO and ETC Models as well as all other mandatory Innovation Center models, including the IOTA model.

We are finalizing revised titles for 42 CFR part 512 and subpart A that refer to ''Standard Provisions for *Mandatory* Innovation Center Models.'' We are revising § 512.100(a)—''Basis''—to provide that the standard provisions apply to ''certain'' Innovation Center models. At § 512.100(b)—''Scope''—we are adding language to provide that the standard provisions apply to the RO Model, the ETC Model, and to Innovation Center Models ''for which participation by Model participants is mandatory.''

D. Provisions Revising Certain Definitions

We proposed to amend the definition of ''Innovation Center model'' at 42 CFR 512.110 by replacing the specific references to the RO and ETC Models with a definition consistent with section 1115A of the Act and intended to encompass all Innovation Center models. We proposed to amend the definition for ''Innovation Center model'' to read as follows: ''an innovative payment and service delivery model tested under the authority of section 1115A(b) of the Act, including a model expansion under section 1115A(c) of the Act.''

We proposed to add a new definition of the term ''governing documentation'' at § 512.110 to mean, ''the applicable Federal regulations, and the model-specific participation agreement, cooperative agreement, and any addendum to an existing contract with CMS, that collectively specify the terms of the Innovation Center model.'' We proposed to add a new definition, ''standard provisions for Innovation Center models,'' at § 512.110 to mean the provisions codified in 42 CFR part 512 subpart A. We proposed to add a new definition, ''performance period,'' at § 512.110 to mean, ''the period of time during which an Innovation Center model is tested and model participants are held accountable for cost and quality of care; the performance period for each Innovation Center model is specified in the governing documentation.''

Further, we proposed to amend the definitions of ''Innovation Center model activities,'' ''model beneficiary,'' and ''model participant'' to pertain to all ''Innovation Center models,'' as we proposed to define that term, instead of just the models previously implemented under part 512. As such, we proposed

to define ''Innovation Center model activities'' to mean ''any activities affecting the care of model beneficiaries related to the test of the Innovation Center model.'' We proposed to define ''model beneficiary'' to mean ''a beneficiary attributed to a model participant or otherwise included in an Innovation Center model.'' We proposed to define ''model participant'' to mean ''an individual or entity that is identified as a participant in the Innovation Center model.''

We invited public comment on these proposed changes to the definitions of ''Innovation Center model,'' ''Innovation Center model activities,'' ''model beneficiary,'' and ''model participant'' and the proposed definitions of ''governing documentation,'' ''standard provisions for Innovation Center models,'' and ''performance period.''

Comment: We received a comment that was supportive of our proposed definitions.

Response: We appreciate the commenter's support of our proposed definitions.

After consideration of the public comment we received, we are finalizing the proposed revisions to the definitions at § 512.110 without modification.

E. Proposed Reconsideration Review Process

We proposed to add a new § 512.190 to part 512 subpart A to codify a reconsideration review process, based on processes implemented under current Innovation Center models. The process would enable model participants to contest determinations made by CMS in certain Innovation Center models, where model participants would not otherwise have a means to dispute determinations made by CMS. We proposed at § 512.190(a)(1) that such a reconsideration process would apply only to Innovation Center models that waive section 1869 of the Act, which governs determinations and appeals in Medicare, or where section 1869 would not apply because model participants are not Medicare-enrolled. We proposed at § 512.190(a)(2) that only model participants may utilize the dispute resolution process, unless the governing documentation for the Innovation Center model states otherwise. Such limitations with respect to such models are, we believe, appropriate, because with respect to such models, model participants do not have another means to dispute determinations made by CMS. We proposed to codify a reconsideration review process in regulation in order to have a transparent and consistent method of reconsideration for model participants participating in models that do not utilize the standard reconsideration process outlined in section 1869 of the Act.

This proposed reconsideration review process would be utilized where a model-specific determination has been made and the affected model participant disagrees with, and wishes to challenge, that determination. Each Innovation Center model features a unique payment and service delivery model, and, as such, requires its own model-specific determination process. Each Innovation Center model's governing documentation details the model-specific determinations made by CMS, which may include, but are not limited to, model-specific payments, beneficiary attribution, and determinations regarding remedial actions. Each Innovation Center model's governing documentation also includes specific details about when a determination is final and may be disputed through the model's reconsideration review processes.

We proposed at § 512.190(b) that model participants may request reconsideration of a determination made by CMS in accordance with an Innovation Center model's governing documentation only if such reconsideration is not precluded by section 1115A(d)(2) of the Act, part 512 subpart A, or the model's governing documentation. A model participant may challenge, by requesting review by a CMS reconsideration official, those final determinations made by CMS that are not precluded from administrative or judicial review. We proposed at § 512.190(b)(i) that the CMS reconsideration official would be someone who is authorized to receive such requests and was not involved in the initial determination issued by CMS or, if applicable, the timely error notice review process. We proposed at § 512.190(b)(ii) that the reconsideration review request would be required to include a copy of CMS's initial determination and contain a detailed written explanation of the basis for the dispute, including supporting documentation. We proposed at § 512.190(b)(iii) that the request for reconsideration would have to be made within 30 days of the date of CMS' initial determination for which reconsideration is being requested via email to an address as specified by CMS in the governing documentation. At § 512.190(b)(2), we proposed that requests that do not meet the requirements of paragraph (b)(1) would be denied.

We proposed at § 512.190(b)(3) that the reconsideration official would send a written acknowledgement to CMS and to the model participant requesting reconsideration within 10 business days of receiving the reconsideration request. The acknowledgement would set forth the review procedures and a schedule that would permit each party an opportunity to submit position papers and documentation in support of its position for consideration by the reconsideration official.

We proposed to codify at § 512.190(b)(4) that, to access the reconsideration process for a determination concerning a model-specific payment where the Innovation Center model's governing documentation specifies an initial timely error notice process, the model participant must first satisfy those requirements before submitting a reconsideration request under this process. Should a model participant fail to timely submit an error notice with respect to a particular model-specific payment, we proposed that the reconsideration review process would not be available to the model participant with regard to that model-specific payment.

We proposed to codify standards for reconsideration at § 512.190(c). First, during the course of the reconsideration, we proposed that both CMS and the party requesting the reconsideration must continue to fulfill all responsibilities and obligations under the governing documentation during the course of any dispute arising under the governing documentation. Second, the reconsideration would consist of a review of documentation timely submitted to the reconsideration official and in accordance with the standards specified by the reconsideration official in the acknowledgement at § 512.190(b)(3). Finally, we proposed that the model participant would bear the burden of proof to demonstrate with clear and convincing evidence to the reconsideration official that the determination made by CMS was inconsistent with the terms of the governing documentation.

We proposed to codify at § 512.190(d) that the reconsideration determination would be an on-the-record review. By this, we mean a review that would be conducted by a CMS reconsideration official who is a designee of CMS who is authorized to receive such requests under proposed § 512.190(b)(1)(i), of the position papers and supporting documentation that are timely submitted and in accordance with the schedule specified under proposed § 512.190(b)(3)(ii) and that meet the standards of submission under proposed § 512.190(b)(1) as well as any

documents and data timely submitted to CMS by the model participant in the required format before CMS made the initial determination that is the subject of the reconsideration request. We proposed at § 512.190(d)(2) that the reconsideration official would issue to the parties a written reconsideration determination. Absent unusual circumstances, in which the reconsideration official would reserve the right to an extension upon written notice to the model participant, the reconsideration determination would be issued within 60 days of CMS's receipt of the timely filed position papers and supporting documentation in accordance with the schedule specified under proposed § 512.190(b)(3)(ii). Under proposed § 512.190(d)(3), the determination made by the CMS reconsideration official would be final and binding 30 days after its issuance, unless the model participant or CMS were to timely request review of the reconsideration determination by the CMS Administrator in accordance with §§ 512.190(e)(1) and (2).

We proposed to codify at § 512.190(e) a process for the CMS Administrator to review reconsideration determinations made under § 512.190(d). We proposed that either the model participant or CMS may request that the CMS Administrator review the reconsideration determination. The request to the CMS Administrator would have to be made via email, within 30 days of the reconsideration determination, to an email address specified by CMS. The request would have to include a copy of the reconsideration determination, as well as a detailed written explanation of why the model participant or CMS disagrees with the reconsideration determination. The CMS Administrator would promptly send the parties a written acknowledgement of receipt of the request for review. The CMS Administrator would send the parties notice of whether the request for review was granted or denied. If the request for review is granted, the notice would include the review procedures and a schedule that would permit each party to submit a brief in support of the party's positions for consideration by the CMS Administrator. If the request for review is denied, the reconsideration determination would be final and binding as of the date of denial of the request for review by the CMS Administrator. If the request for review by the CMS Administrator is granted, the record for review would consist solely of timely submitted briefs and evidence contained in the record of the proceedings before the reconsideration official and evidence as set forth in the documents and data described in proposed § 512.190(d)(1)(ii); the CMS Administrator would not consider evidence other than information set forth in the documents and data described in proposed § 512.190(d)(1)(ii). The CMS Administrator would review the record and issue to the parties a written determination that would be final and binding as of the date the written determination is sent.

We invited public comment on the proposed reconsideration review process for Innovation Center models.

We received no comments on this proposal and are finalizing this provision as proposed with a few technical changes for clarity.

III. Increasing Organ Transplant Access (IOTA) Model

A. Introduction

In this final rule, we finalize the IOTA Model, a new mandatory Medicare alternative payment model that will be tested under the authority of the Innovation Center at section 1115A(b) of the Act, that will begin on July 1, 2025, and end on June 30, 2031. The IOTA Model will test whether using performance-based incentive payments in the form of upside risk payments and downside risk payments to and from transplant hospitals selected to participate in the model increases the number of kidney transplants furnished to patients with ESRD, thereby reducing Medicare expenditures while preserving or enhancing quality of care.

The goal of the performance-based payments is to increase the number of kidney transplants furnished to ESRD patients placed on a kidney transplant hospital's waitlist; encourage investments in value-based care and quality improvement activities, particularly those that promote an equitable kidney transplant process prior to, during, and post transplantation for all patients; encourage better use of the current supply of deceased donor organs and greater provider and community collaborations to address the medical and non-medical needs of patients; and increased awareness, education, and support for living donations. The IOTA Model payment structure will also promote IOTA participant accountability by linking performance-based payments to quality. We theorize that increasing the number of kidney transplants furnished to ESRD patients on the participating hospitals' waitlists will reduce Medicare expenditures by reducing dialysis expenditures and avoidable health care service utilization and will improve the quality of life for patients with ESRD.

As discussed in section III.B of this final rule, studies show that kidney transplant hospitals are underutilizing donor kidneys and have become more conservative in accepting organs for transplantation, with notable variation by region and across transplant hospitals.[10] The IOTA Model aims to address these access and equity problems through financial incentives that reward IOTA participants that improve their kidney organ offer acceptance rate ratios over time and hold them financially accountable for not doing so. The IOTA Model's payment structure includes upside and downside performance-based incentive payments (''upside risk payment'' or ''downside risk payment'') for kidney transplant hospitals selected to participate in the IOTA Model (''IOTA participant'') that are tied to performance on achievement, efficiency, and quality domains.

The achievement domain will assess the number of kidney transplants performed relative to a participant-specific target, with performance on this domain being worth up to 60 points. The efficiency domain will assess kidney organ offer acceptance rate ratios relative to a national rate for all kidney transplant hospitals, including those not selected to participate in the model, to 20 points. or to the IOTA participant's own past kidney organ offer acceptance rate ratio, with performance on this domain being worth up to 20 points. The quality domain will assess performance based on post-transplant outcomes, with performance on this domain being worth up to 20 points. The achievement domain will be weighted more heavily than the other two domains because increasing the number of transplants is a key goal of the model and will be a primary factor in determining the amount of the performance-based payment.

The final performance score for each IOTA participant will be the sum of the points earned across the achievement domain, efficiency domain, and quality domain. The final performance score will determine whether an upside risk payment or downside risk payment would be owed and the amount of such payment. Specifically:

[10] Mohan, S., Chiles, M.C., Patzer, R.E., Pastan, S.O., Husain, S.A., Carpenter, D.J., Dube, G.K., Crew, R.J., Ratner, L.E., & Cohen, D.J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International, 94*(1), 187–198. *https://doi.org/10.1016/j.kint.2018.02.016.*

• For PY 1, if an IOTA participant has a final performance score between 60 and 100 points, it would qualify for the upside risk payment in accordance with the proposed calculation methodology described in section III.C.6.c.(2)(a) of this final rule (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 beneficiaries with Medicare FFS as a primary or secondary payer during the PY).

• For PY 1, if an IOTA participant has a final performance score below 60, it would fall into a neutral zone where no upside risk payment and no downside risk payment would apply.

• For PY 2 and each subsequent PY (PYs 2–6), if an IOTA participant achieves a final performance score of 41 to 59 points, it would fall into a neutral zone where no upside risk payment and no downside risk payment would apply.

• For PY 2 and each subsequent PY, if an IOTA participant achieves a final performance score of 40 points or below, it would be subject to the downside risk payment in accordance with the calculation methodology described in section III.C.6.c.(2)(b) of this final rule (40 minus final performance score, then divided by 40, then multiplied by $2,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to beneficiaries with Medicare FFS as a primary or secondary payer during the PY).

We recognize the complexity of the transplant ecosystem, which requires coordination between transplant hospitals, other health care providers, organ procurement organizations (OPOs), patients, potential donors, and their families. The IOTA Model does not prescribe or require specific processes or policy approaches that each selected IOTA participant must implement for purposes of the model test.

We believe the IOTA Model will complement other efforts in relation to the transplant ecosystem to enhance health and safety outcomes, increase transparency, increase the number of transplants, and reduce disparities. We also believe that the payment methodology will act in concert with efforts that are currently under development by HRSA to increase the numbers of both deceased and living donor organ transplants.

This model falls within a larger framework of activities initiated by the Federal Government during the past several years and planned for the upcoming year to enhance the donation, procurement, and transplantation of solid organs. This Federal collaborative, called the Organ Transplantation Affinity Group (OTAG), is a coordinated group working together to strengthen accountability, equity, and performance in organ donation, procurement, and transplantation.[11]

B. Background

A review of the literature on kidney transplantation shows that the increasing numbers of kidney transplants is unable to keep pace with the increasing need for organs and is discussed in section III.B.3.d of this final rule.[12] While more people die waiting for a kidney transplant, the short- and long-term outcomes of patients who undergo kidney transplantation have improved, despite both recipients and donors increasing in age and adverse health conditions.[13] Recent studies show that transplant hospitals have become more conservative in accepting organs for transplantation when offered for specific patients, avoiding the use of less-than-ideal organs on account of perceived risk.[14] Wide variation among geographic regions and transplant hospitals in rates of kidney transplantation, along with access and equity issues, raises the need to hold kidney transplant hospitals accountable for performance.[15] The IOTA Model includes a two-sided performance-based payment structure that rewards IOTA participants for high performance in the achievement, efficiency, and quality domains, and imposes financial accountability on IOTA participants that perform poorly on those domains. We proposed the IOTA Model as a complement to wider efforts aimed at transplant ecosystem performance and equity improvements as discussed in section III.B of the proposed rule. Ultimately, we seek a set of interventions that focus on ESRD patients in need of a kidney transplant. In section III.B of the proposed rule, we summarized the transplant ecosystem and HHS oversight within CMS and HRSA related to kidney transplantation, highlight related initiatives and priorities nationally, and outlined our rationale for the proposed IOTA Model informed by literature, data, and studies.

1. The Transplant Ecosystem

Kidney transplantation occurs within an overall organ donation and transplantation system (also known and referred to as the transplant ecosystem) that comprises a vast network of institutions dedicated to ensuring that patients are evaluated and, if appropriate, placed onto the organ transplant waitlist, and that those on the organ transplant waitlist receive lifesaving organ transplants. Transplantation of livers, hearts, lungs, and other organs is also well established within the U.S. health care system. The transplant ecosystem includes the Organ Procurement and Transplantation Network (OPTN); Organ Procurement Organizations (OPOs); transplant hospitals and providers; histocompatibility laboratories that provide blood, tissue, and antibody testing for the organ matching process; and patients, including ESRD patients in need of a transplant, their families, and caregivers.[16] For kidney transplantation, it also includes ESRD facilities, commonly known as dialysis facilities.

The National Organ Transplant Act of 1984, referred to herein as NOTA, established the OPTN, with HHS oversight, to manage and operate the national organ transplantation system (42 U.S.C. 274). The OPTN is a network that coordinates the nation's organ procurement, distribution, and transplantation systems.

Organ Procurement Organizations (OPOs) are non-profit organizations operating under contract with the Federal Government that are charged, under section 371(b) of the Public

[11] Moody-Williams, J.D., & Nair, S. (2023, September 15). Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance | CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

[12] Penn Medicine News. (2020, December 16). *Too Many Donor Kidneys Are Discarded in U.S. Before Transplantation—Penn Medicine.* (2020, December 16). *www.pennmedicine.org. https://www.pennmedicine.org/news/news-releases/2020/december/too-many-donor-kidneys-are-discarded-in-us-before-transplantation www.pennmedicine.org.*

[13] Hariharan, S., Israni, A.K., & Danovitch, G. (2021). Long-Term Survival after Kidney Transplantation. *New England Journal of Medicine, 385*(8), 729–743. *https://doi.org/10.1056/nejmra2014530.*

[14] Stewart, D.E., Garcia, V.C., Rosendale, J.D., Klassen, D.K., & Carrico, B.J. (2017). Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. *Transplantation, 101*(3), 575–587. *https://doi.org/10.1097/tp.0000000000001539.*

[15] Mohan, S., Chiles, M.C., Patzer, R.E., Pastan, S.O., Husain, S.A., Carpenter, D.J., Dube, G.K., Crew, R.J., Ratner, L.E., & Cohen, D.J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International, 94*(1), 187–198. *https://doi.org/10.1016/j.kint.2018.02.016.*

[16] Moody-Williams, J.D., & Nair, S. (2023, September 15). Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance | CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

Health Service Act (PHS Act, 42 U.S.C. 273(b)) with activities including, but not limited to, identifying potential organ donors, providing for the acquisition and preservation of donated organs, the equitable allocation of donated organs, and the transportation of donated organs to transplant hospitals. Section 371(b) of the Public Health Services Act requires that an OPO must have a defined service area, a concept that is defined at 42 CFR part 486 subpart G as the Donation Service Area (DSA). Section 1138(b) of the Act states that the Secretary may not designate more than one OPO to serve each DSA. There are currently 56 OPOs that serve the United States and Puerto Rico.

Section 1138(b) of the Act lays out the requirements that an OPO must meet for organ acquisition costs to be payable under Title XVIII and Title XIX. Separately, CMS sets out the components of allowable Medicare organ acquisition costs at 42 CFR 413.402(b). Allowable organ acquisition costs are those costs incurred in the acquisition of organs intended for transplant, and include, but are not limited to: costs associated with special care services, the surgeon's fee for excising the deceased donor organ from the donor patient (limited to $1,250 for kidneys), operating room and other inpatient ancillary services provided to the living or deceased donor, organ preservation and perfusion costs, and donor and beneficiary evaluation. OPOs and transplant hospitals may incur organ acquisition costs and include these and some additional administrative and general costs on the Medicare cost report.

The CMS conditions for coverage for OPOs at 42 CFR 486.322 require an OPO to have written agreements with 95 percent of the Medicare and Medicaid certified hospitals and critical access hospitals in its DSA that have a ventilator and an operating room and have not been granted a waiver to work with another OPO. These hospitals, known as donor hospitals, are required by the CMS conditions of participation for hospitals at 42 CFR 482.45 to have an agreement with an OPO under which the donor hospital must notify the OPO of patients who are expected to die imminently and of patients who have died in the hospital. (Under the hospital conditions of participation, such an agreement is required of all hospitals that participate in Medicare.) Also, under the hospital conditions of participation, donor hospitals are responsible for informing donor patient families of the option to donate organs, tissues, and eyes, or to decline to donate; and to work collaboratively with the OPO to educate hospital staff on donation, improve its identification of potential donors, and work with the OPO to manage the potential donor patient while testing and placement of the potential donor organ occurs.

At 42 CFR 482.70, CMS defines a transplant hospital as ''a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients,'' and a transplant program as ''an organ-specific transplant program within a transplant hospital,'' as so defined. In accordance with 42 CFR 482.98(b), a transplant program must have a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation. The transplant surgeon is responsible for providing surgical services related to transplantation, and the transplant physician is responsible for providing and coordinating transplantation care.

In accordance with CMS' Conditions for Coverage (CfC) for ESRD Facilities at 42 CFR part 494, ESRD facilities are charged with delivering safe and adequate dialysis to ESRD patients, and, among other requirements, informing patients of their treatment modalities, including dialysis and kidney transplantation. The CfCs require ESRD facilities to conduct a patient assessment that includes evaluation of suitability for referral for transplantation, based on criteria developed by the prospective transplantation center and its surgeon(s). General nephrologists refer patients for evaluation for kidney transplants.[17] Candidates for kidney transplant undergo a rigorous evaluation by a transplant program prior to placement on a waitlist, involving evaluation by a multidisciplinary team for conditions pertaining to the potential success of the transplant, the possibility of recurrence, and surgical issues including frailty, obesity, diabetes and other causes of ESRD, infections, malignancies, cardiac disease, pulmonary disease, peripheral arterial disease, neurologic disease, hematologic conditions, and gastrointestinal and liver disease and an immunological assessment; a psychosocial assessment; assessment of adherence behaviors; and tobacco counseling.[18]

Once placed on the waitlist, potential recipients must maintain active status to be eligible to receive a deceased donor transplant.[19] An individual may receive a status of 'inactive' if they are missing lab results, contact information, or any of the other requirements that would be necessary for them to receive an organ transplant if offered. An individual may only receive an organ offer if they have a status of 'active.' [20] Each transplant hospital has its own waitlist, and patients can attempt to be placed on multiple waitlists; OPTN maintains a national transplant waiting list that encompasses the waitlists for all kidney transplant hospitals.[21] [22] Individuals already on dialysis continue to receive regular dialysis treatments while waiting for an organ to become available. After surgery, a transplant nephrologist manages the possible outcomes of organ rejection and infection, and other medical complications.[23]

2. HHS Oversight and Priorities

HRSA, which oversees the OPTN, and CMS play a vital role in protecting the health and safety of Americans as they engage with the U.S. health care system.[24] The OPTN operates a complex network of computerized interactions whereby specific deceased donor organs get matched to individual patients on the national transplant waiting list. The Scientific Registry of Transplant Recipients (SRTR), operated under

[17] Virmani, S., & Asch, W.S. (2020). The Role of the General Nephrologist in Evaluating Patients for Kidney Transplantation: Core Curriculum 2020. *American Journal of Kidney Diseases, 76,* 567–579. *https://doi.org/10.1053/j.ajkd.2020.01.001.*

[18] Chadban, S.J., Ahn, C., Axelrod, D.A., Foster, B.J., Kasiske, B.L., Kher, V., Kumar, D., Oberbauer, R., Pascual, J., Pilmore, H.L., Rodrigue, J.R., Segev, D.L., Sheerin, N.S., Tinckam, K.J., Wong, G., & Knoll, G.A. (2020). KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation. *Transplantation, 104*(4S1), S11. *https://doi.org/10.1097/TP.0000000000003136.*

[19] National kidney Foundation. (2017, February 10). *The Kidney Transplant Waitlist—What You Need to Know.* National Kidney Foundation. *https://www.kidney.org/atoz/content/transplant-waitlist.*

[20] *The kidney transplant waitlist.* (n.d.). Transplant Living. *https://transplantliving.org/kidney/the-kidney-transplant-waitlist/.*

[21] National kidney Foundation. (2019, June 12). *Understanding the transplant waitlist.* National Kidney Foundation. *https://www.kidney.org/content/understanding-transplant-waitlist.*

[22] National kidney Foundation. (2016, August 4). *Multiple Listing for Kidney Transplant.* National Kidney Foundation. *https://www.kidney.org/atoz/content/multiple-listing.*

[23] *Transplant Nephrology Fellowship.* (n.d.). *www.hopkinsmedicine.org.* Retrieved May 30, 2023, from *https://www.hopkinsmedicine.org/nephrology/education/transplant-fellowship.*

[24] On March 22, 2023, HRSA announced an initiative that included several actions to strengthen accountability and transparency in the OPTN. These actions include modernization of the OPTN information technology system.

contract with HRSA, is responsible for providing statistical and analytic support to the OPTN. Section 373 of the PHS Act requires the operation of the SRTR to support ongoing evaluation of the scientific and clinical status of solid organ transplantation.[25]

CMS oversees and evaluates OPO performance. OPOs must meet performance measures and participate in, and abide by certain rules of, the OPTN.[26] The PHS Act requires the Secretary to establish outcome and process performance measures to recertify OPOs (Part H section 371; 42 U.S.C. 273). CMS has promulgated the OPO CfCs at 42 CFR part 486 subpart G.

Additionally, OPTN policies specify that OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold would be reviewed by the OPTN Membership Professional Standards Committee (MPSC).[27] CMS also conducts oversight of transplant programs, located within transplant hospitals, which must abide by both the hospital and the transplant program conditions of participation (CoPs). CMS contracts with quality improvement entities such as the ESRD Networks and Quality Improvement Organizations to provide technical support to providers and patients seeking improvements in the transplant ecosystem.

Medicare covers certain transplant-related services when provided at a Medicare-approved facility. Medicare Part A covers the costs associated with a Medicare kidney transplant procedure received in a Medicare-certified hospital and any additional inpatient hospital care needed following the procedure, and kidney acquisition costs including kidney registry fees, surgeons' fees for excising a kidney for transplant, and laboratory tests associated with the evaluation of a Medicare transplant candidate. The evaluation or preparation of a living kidney donor, the living donor's donation of the kidney, and postoperative recovery services directly related to the living donor's kidney donation are covered under Medicare. In addition, deductible and coinsurance requirements do not apply to living donors for services furnished to an individual in connection with the donation of a kidney for transplant surgery for a Medicare beneficiary. Medicare Part B coverage includes the surgeon's fees for performing the kidney transplant procedure and perioperative care. Medicare Part B also covers physician services for the living kidney donor without regard to whether the service would otherwise be covered by Medicare. Part A and Part B share responsibility for covering blood, including packed red blood cells, blood components and the cost of processing and receiving blood.

Medicare Part B covers immunosuppressive drugs following an organ transplant for which payment is made under Title XVIII. Immunosuppressive drugs following an organ transplant are covered by Part D when an individual did not have Part A at the time of the transplant. Beneficiaries who have Medicare due to ESRD alone lose Medicare coverage 36 months following a successful kidney transplant. Section 402(a) of the Consolidated Appropriations Act (CAA) of 2021 added section 1836(b) of the Act to provide coverage for immunosuppressive drugs beginning January 1, 2023, for eligible individuals whose eligibility for Medicare based on ESRD ends by reason of section 226A(b)(2) of the Act for those three-years post kidney transplant. Under section 1833 of the Act, the amounts paid by Medicare for immunosuppressive drugs are equal to 80 percent of the applicable payment amount; beneficiaries are thus subject to a 20 percent coinsurance for immunosuppressive drugs covered by both Part B and the Medicare Part B Immunosuppressive Drug Benefit (Part B–ID).

3. Federal Government Initiatives To Enhance Organ Transplantation

a. CMS Regulatory Initiatives To Enhance Organ Transplantation

On September 30, 2019, we published the final rule, ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51732). The rulemaking, in part, aimed to address the concern that too many organs are being discarded that could be transplanted successfully, including hearts, lungs, livers, and kidneys. This rule implemented changes to the transplant program regulations, eliminating requirements for re-approval of transplant programs pertaining to data submission, clinical experience, and outcomes. We believed that the removal of these requirements aligned with our goal of increasing access to kidney transplants by increasing the utilization of organs from deceased donors and reducing the organ discard rate (84 FR 51732). We sought improved organ procurement, greater organ utilization, and reduction of burden for transplant hospitals, while still maintaining the importance of safety in the transplant process.

On December 2, 2020, we issued a final rule titled, ''Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations'' (85 FR 77898), which revised the OPO CfCs by replacing the previous outcome measures with new transparent, reliable, and objective outcome measures. In modifying the metrics used for assessing OPO performance, we sought to promote greater utilization of organs that might not otherwise be recovered or used due to perceived organ quality.[28]

While these regulatory changes went into effect with the goal of improving the performance of transplant hospitals and OPOs and to promote the procuring of organs and delivering them to prospective transplant recipients, we acknowledged the need for improvements in health, safety, and outcomes across the transplant ecosystem, including in transplant programs, OPOs, and ESRD facilities.[29] [30] In particular, we recognize that further action must be taken to address health disparities and lower rates of transplantation for underserved populations observed across transplant hospitals.

We published a request for information in the **Federal Register** on

[25] *Mission, Vision, and Values.* (n.d.). *www.srtr.org. https://www.srtr.org/about-srtr/mission-vision-and-values/.*

[26] U.S. Congress. (1934) United States Code: Social Security Act, 42 U.S.C. 301–Suppl. 4 1934.

[27] Bylaws–OPTN. (n.d.). Optn.*transplant.hrsa.gov.* Retrieved September 13, 2024, from *https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.*

[28] The Organ Procurement Organizations Annual Public Aggregated Performance Report for 2023 is available at *https://www.cms.gov/files/document/opo-annual-public-performance-report-2023.pdf.*

[29] One study—Doby, B. One study—Doby, B. One study—Doby, B. One study showed that deceased donor organ donation increased during 2019, during the period of public debate about regulating OPO performance. *See* Doby, B.L., Ross-Driscoll, K., Shuck, M., Wadsworth, M., Durand, C.M., & Lynch, R.J. (2021). Public discourse and policy change: Absence of harm from increased oversight and transparency in OPO Performance. *American Journal of Transplantation, 21*(8), 2646–2652. *https://doi.org/10.1111/ajt.16527.*

[30] In addition, CMS finalized a policy in the final rule for FY 2023 for the Medicare Physician Fee Schedule that Medicare Part A and Part B payment can be made for dental or oral examinations, including necessary treatment, performed as part of a necessary workup prior to organ transplant surgery. In the final rule, CMS describes certain dental services as inextricably linked and integral to the clinical success of organ transplantation. (87 FR 69671–69675).

December 3, 2021, titled ''Request for Information: Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Facilities'' (86 FR 68594) (hereafter known as the ''Transplant Ecosystem RFI''). This RFI solicited public comments on potential changes to the requirements that transplant programs, OPOs, and ESRD facilities must meet to participate in the Medicare and Medicaid programs. Specifically, we solicited public comments on ways to:

- Continue to improve systems of care for all patients in need of a transplant;
- Increase the number of organs available for transplant for all solid organ types;
- Encourage the use of dialysis in alternate settings or modalities over in-center hemodialysis where clinically appropriate and advantageous;
- Ensure that the CMS and HHS policies appropriately incentivize the creation and use of future new treatments and technologies; and
- Harmonize requirements across government agencies to facilitate these objectives and improve quality across the organ donation and transplantation ecosystem.

We also solicited information related to opportunities, inefficiencies, and inequities in the transplant ecosystem and what can be done to ensure all segments of our healthcare systems are invested and accountable in ensuring improvements to organ donation and transplantation rates (86 FR 68596). The Transplant Ecosystem RFI focused on questions in the areas of transplantation, kidney health and ESRD facilities, and OPOs. For transplant programs, specific topics included transplant program CoPs, patient rights, and equity in organ transplantation and organ donation (86 FR 68596). For kidney health and ESRD facilities, topics included maintaining and improving health of patients, ways to identify those at risk of developing chronic kidney disease (CKD), improving detection rates of CKD, and ways to close the CKD detection, education, and care health equity gap (86 FR 68599). Other topics included home dialysis, dialysis in alternative settings such as nursing homes and mobile dialysis, and alternate models of care (86 FR 68600). For OPOs, specific topics included assessment and recertification, organ transport and tracking, the donor referral process, organ recovery centers, organ discards, donation after cardiac death, tissue banks, organs for research, and vascular composite organs. (86 FR 68601 through 68606).

The Transplant Ecosystem RFI followed three executive orders addressing health equity that were issued by President Biden on January 20 and January 21, 2021—

- Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (E.O. 13985, 86 FR 7009, January 20, 2021);
- Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation (E.O. 13988, 86 FR 7023, January 25, 2021); and
- Executive Order on Ensuring an Equitable Pandemic Response and Recovery (E.O. 13995, 86 FR 7193, January 26, 2021).

The RFI was among several issued by CMS in 2021 to request public comment on ways to advance health equity and reduce disparities in our policies and programs.

CMS's regulatory initiatives since 2018 pertaining to organ donation and transplantation have included final rules modifying CoPs and CfCs for transplant programs (84 FR 51732) and OPOs (85 FR 77898), respectively, and our recent RFI on transplant program CoPs, OPO CfCs, and the ESRD facility CfCs (86 FR 68594). These regulations and RFIs have sought to foster greater health and safety for patients, greater transparency for all patients, increases in organ donation and transplantation, and reduced disparities in organ donation and transplantation. Through these regulations, we are working to attain these goals by designing and implementing policies that improve health for all people affected by the transplant ecosystem.

b. CMS Innovation Center Payment Models

The Innovation Center is currently pursuing complementary alternative payment model tests—the ESRD Treatment Choices (ETC) Model and the Kidney Care Choices (KCC) Model—aimed at enhancing kidney transplantation and improving health-related outcomes for patients with late-stage CKD and ESRD, thereby reducing costs to the Medicare program. The impetus for the ETC and KCC Models originated with evaluation findings for the earlier Comprehensive ESRD Care (CEC) Model, which ran from October 2015 through March 2021, that showed large dialysis organizations achieving positive clinical and financial outcomes relating to services to Medicare beneficiaries receiving dialysis, though the CEC Model did not achieve net savings to Medicare.[31] The CEC Model focused on patients being treated in ESRD facilities, with no explicit incentives to encourage increases in kidney transplantation.

The ETC and KCC Models have engaged a broader range of health care providers beyond ESRD facilities, including nephrology professionals and transplant providers, and address transplantation. Each model includes direct financial incentives for increasing the number of kidney transplants.

The ETC Model, which began January 1, 2021, and which is scheduled to end on June 30, 2027, is a mandatory model that tests whether greater use of home dialysis and kidney transplantation for Medicare beneficiaries with ESRD reduces Medicare expenditures while preserving or enhancing the quality of care furnished to those beneficiaries. We established requirements for the ETC Model in the Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures final rule (85 FR 61114 through 61381). These requirements are codified at 42 CFR subpart C. The ETC Model tests the effects of certain Medicare payment adjustments to participating ESRD facilities and Managing Clinicians (clinicians who manage ESRD beneficiaries and bill the Monthly Capitation Payment (MCP)).

The payment adjustments are designed to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance quality of care. Under the ETC Model, CMS makes upward adjustments to certain payments under the ESRD Prospective Payment System (PPS) to certain dialysis facilities on home dialysis claims, and upward adjustments to the MCP paid to certain Managing Clinicians on home dialysis-related claims (85 FR 61117). In addition, CMS makes upward and downward adjustments to PPS payments to participating ESRD facilities and to the MCP paid to participating Managing Clinicians based on the Participant's home dialysis rate and transplant waitlisting and living

[31] The results of the CMS-sponsored evaluation of the CEC Model are available at *https://innovation.cms.gov/innovation-models/comprehensive-esrd-care.* The 5-year model test reduced Medicare expenses by $217 million, or 1.3 percent relative to the pre-CEC period. These results do not account for shared savings payments to the model participants. There was a 3 percent decrease in the number of hospitalizations and a 0.4 percent increase in the number of outpatient dialysis sessions for Medicare beneficiaries in CEC compared to non-CEC beneficiaries. In addition, the CEC Model improved key quality outcomes.

donor transplant rate (85 FR 61117). The ETC Model's objectives, as described in the final rule, include supporting paired donations and donor chains, and reducing the likelihood that potentially viable organs are discarded (85 FR 61128). The ETC Model was updated by the final rule dated November 8, 2021, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' and the final rule dated November 7, 2022, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (87 FR 67136). We finalized further modifications to the ETC Model related to the availability of administrative review of an ETC Participant's targeted review request in the final rule issued on November 6, 2023, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (88 FR 76345). As of the second model evaluation report covering the first two years of the model, the model has not shown statistically significant results as home dialysis grew similarly across ETC areas and the comparison group and no statistically significant differences in waitlisting and living donor transplant rates. As noted earlier, CMS will continue to evaluate the effectiveness of the ETC Model.

CMS is also operating the ETC Learning Collaborative, which is focused on increasing the availability of deceased donor organs for transplantation.[32] The ETC Learning Collaborative regularly convenes ETC Participants, transplant hospitals, OPOs, and large donor hospitals, with the goal of using learning and quality improvement techniques to systematically spread the best practices of the highest performing organizations. CMS is employing quality improvement approaches to improve performance by collecting and analyzing data to identify the highest performers, and to help others to test, adapt and spread the best practices of these high performers throughout the entire national organ recovery system (85 FR 61346).

The KCC Model, which began its performance period on January 1, 2022, and is scheduled to end on December 31, 2026, is a voluntary model that also builds upon the CEC Model structure to encourage health care providers to better manage the care for Medicare beneficiaries with CKD stages 4 and 5 and ESRD, delay the onset of dialysis, and incentivize kidney transplantation. Various entities are participating in the KCC Model, including nephrologists and nephrology practices, dialysis facilities, and other health care providers. The participating entities receive a bonus payment for each aligned beneficiary who receives a kidney transplant, so long as the transplant remains successful over a certain time period. CMS plans to continue to evaluate the effectiveness of the ETC and KCC Models in achieving clinical goals, improving quality of care, and reducing Medicare costs.[33]

The IOTA Model will complement the ETC and KCC Models and expand kidney model participation to hospitals, which are a key player in the transplant ecosystem, to test whether two-sided risk payments based on performance increase access to kidney transplants for ESRD patients placed on the waitlists of participating transplant hospitals.

c. HRSA Initiatives Involving Kidney Transplants

NOTA established the OPTN almost 40 years ago to coordinate and operate the nation's organ procurement, allocation, and transplantation system. There are about 400 member organizations that comprise the OPTN. Section 372(b)(2)(A) of the PHS Act charges the OPTN with establishing a national list of individuals who need organs and a national computer system to match organs with individuals on the waitlist. HRSA has also undertaken efforts in alignment with CMS efforts and Federal Government initiatives to improve accountability in OPTN functions. On March 22, 2023, HRSA launched the OPTN Modernization Initiative to strengthen accountability, equity, and performance in the organ donation and transplantation system through a focus on five key areas: technology, data transparency, governance, operations, and quality improvement and innovation.[34] The OPTN Modernization Initiative was further supported by the Securing the U.S. Organ Procurement and Transplantation Network Act (Pub. L. 118–14), which included several key provisions proposed in the President's Fiscal Year 2024 Budget and was signed into law on September 22, 2023.[35] The new law expressly authorizes HHS to make multiple awards to different entities, which could enable the OPTN to benefit from best-in-class vendors and provide a more efficient system that strengthens oversight and improves patient safety.

Effective July 14, 2022, revisions to OPTN policies were made related to the Transplant Program Performance to establish new criteria for identification of transplant programs that enter MPSC performance review based on the following criteria:[36]

- The transplant program's 90-day post-transplant graft survival hazard ratio is greater than 1.75 during the 2.5-year time period; or
- The transplant program's 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival hazard ratio is greater than 1.75 during a 2.5-year period.

Transplant programs that meet either of the criteria, as reported by the SRTR, must participate in the OPTN Membership and Professional Standards Committee (MPSC) performance review, which may require the member to take appropriate actions to determine if the transplant program has demonstrated sustainable improvement, including, but not limited to—

- Providing information about the program structure, procedures, protocols and quality;
- Review processes;
- Adopting and implementing a plan for improvement;
- Participating in an informal discussion with MPSC members; and
- Participating in a peer visit.

The MPSC would continue to review the transplant program under the performance review until the MPSC determines that the transplant program has made sufficient and sustainable improvements to avoid risk to public

[32] Centers for Medicare & Medicaid Services. *https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model.*

[33] The evaluation report for the first two years (2021, 2022) of the ETC Model is available at *https://www.cms.gov/priorities/innovation/innovation-models/esrd-treatment-choices-model* and the evaluation report for the first year (2022) of the KCC Model is available at *https://www.cms.gov/priorities/innovation/innovation-models/kidney-care-choices-kcc-model.*

[34] *HRSA Announces Organ Procurement and Transplantation Network Modernization Initiative | HRSA.* (n.d.). *www.hrsa.gov.* Retrieved August 20, 2023, from *https://www.hrsa.gov/optn-modernization/march-2023.*

[35] The White House. (2023, September 22). *Bill Signed: H.R. 2544.* The White House. *https://www.whitehouse.gov/briefing-room/legislation/2023/09/22/bill-signed-h-r-2544/.*

[36] OPTN. (n.d.). *Bylaws.* Retrieved September 15, 2024 from *https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.*

health or patient safety. If the MPSC's review determines that a risk to patient health or public safety exists, the MPSC may request that a member inactivate or withdraw a designated transplant program, or a specific component of the program, to mitigate the risk. Transplant programs that do not participate in the MPSC performance review process or fail to act to improve their performance are subject to the policies described in Appendix L of OPTN policies, Reviews and Actions, including the declaration of ''Member Not in Good Standing.'' While being designated ''Member Not in Good Standing'' does not necessarily lead to the closure or removal of that program from receiving reimbursement from Federal health insurance programs, the Secretary can, based on a recommendation from the OPTN Board of Directors, revoke OPTN membership, close an OPTN member, or remove the ability of the member to receive Federal funding from Medicare or Medicaid. Additionally, numerous private payers align with the MPSC metrics and SRTR star rating system that evaluate transplant hospitals on post-transplant performance to create their Center of Excellence (COE) programs. Therefore, MPSC reviews and performance on the MPSC monitoring measures are a powerful regulatory incentive for transplant programs.

In the final rule, dated September 22, 2020, titled ''Removing Financial Disincentives to Living Organ Donation'' (85 FR 59438), HRSA expanded the scope of qualified reimbursable expenses incurred by living donors under the Living Organ Donation Reimbursement Program to include lost wages and dependent care (childcare and elder care) expenses to further the goal of reducing financial barriers to living organ donation. The program previously only allowed for reimbursement of travel, lodging, meals, and incidental expenses. In the final notice, dated September 22, 2020, titled, ''Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Program Eligibility Guidelines,'' HRSA increased the income eligibility threshold under the Living Organ Donation Reimbursement Program from 300 percent to 350 percent of the Federal Poverty Guidelines (85 FR 59531).

3. Rationale for the Proposed IOTA Model

a. Alignment With Federal Government Initiatives and Priorities

For decades, patients and health care providers have confronted an imbalance in the number of transplant candidates and the supply of acceptable donor organs, including kidneys and other organs. Observed variation in access to organ transplantation by geography, race/ethnicity, disability status, and socioeconomic status, as well as the overall performance of the organ transplantation ecosystem, raised the need to make performance improvements and address disparities.[37] Strengthening and improving the performance of the organ transplantation ecosystem is a priority for HHS. To that end, OTAG was established in 2021 by CMS and HRSA and has expanded interagency coordination and collaboration to ''drive improvements in donations, clinical outcomes, system improvement, quality measurement, transparency, and regulatory oversight.'' [38] Collectively, CMS and HRSA seek to—

- Reduce variation of pre-transplant and referral practices; [39]
- Increase availability and use of donated organs;
- Increase accountability for organ procurement and matching;
- Promote equitable access to transplants; and
- Empower patients, families, and caregivers to actively engage in the transplant journey.

As discussed in section III.C. of the proposed rule, we believe the IOTA Model has the potential to substantially increase the number of kidney transplants in a way that enhances fairness for all affected individuals, regardless of socioeconomic status or other factors that limit access to care and negatively affect health outcomes, thereby improving quality of care, reducing costs to Medicare, and prolonging lives. The IOTA Model is complementary to the ETC and KCC Models, and to other CMS and HRSA initiatives, with the collective goal of achieving improvements in processes among transplant hospitals that would spur an increase in both deceased donor and living donor kidney transplantation and reduce population health disparities. The IOTA Model is targeted to kidney transplant programs, but it will test specific modifications for Medicare payment and other programmatic measures that could establish a framework for interventions for transplantation that could potentially be applied to the other solid organ types in the future.

In the following sections of this final rule, we review scientific literature that outlines specific ways to enhance kidney transplantation. Our analysis is focused on kidney transplantation, but we also present findings pertaining to the transplantation of other organs, especially livers. We aim to show how the types of interventions that we proposed might also apply for any future efforts to increase transplant numbers for other organ types, and to continue to pursue the goal of greater equity. We also describe recent efforts from CMS and HRSA to enhance organ transplantation that complement to the IOTA Model's use of upside risk payments and downside risk payments as a policy lever to increase the number of kidney transplants and achieve a fairer distribution. of kidney transplants.

b. End Stage Renal Disease Impact

According to the United States Renal Data System (USRDS), in 2021 about 808,536 people in the United States were living with ESRD, almost double the number in 2001.[40] Prevalence of ESRD varied by Health Service Area (HSA) and ESRD Network.[41] Stratified by age and race/ethnicity, ESRD was consistently more prevalent among older people (65 and older) and in Black people.[42] Diabetes and hypertension are most often the primary cause of ESRD.[43] According to the National Kidney Foundation, these diseases disproportionately affect minority populations, increasing the risk of kidney disease.[44] Year-over-year, incidence of ESRD continues to increase, as the number of patients newly registered increased from 97,856 in 2001 to 134,837 in 2019 and 135,972 in 2021.[45] Studies show that people

[37] Moody-Williams, J.D., & Nair, S. (2023, December 13). Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance | CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

[38] Moody-Williams, J.D., & Nair, S. (2023, December 13). Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance | CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

[39] Pre-transplant/referral practices are inclusive of the referring physician's assessment criteria, patient education, and feedback to the referring physician from the transplant assessment.

[40] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 1. Figure 1.5.

[41] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 1. Figure 1.7.

[42] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 1. Figure 1.8.

[43] United States Renal Data System. 2023. End Stage Renal Disease. Chapter 1. Table 1.3.

[44] National Kidney Foundation. (2016, January 7). *Race, Ethnicity and Kidney Disease.* National Kidney Foundation. *https://www.kidney.org/atoz/content/minorities-KD.*

[45] United States Renal Data System. 2023. End Stage Renal Disease. Chapter 1. Figure 1.1.

with kidney transplants live longer than those who remain on dialysis.[46] [47] Despite these positive outcomes, the percentage of prevalent ESRD patients with a functioning kidney transplant remained relatively stable over the past decade, increasing only slightly from 29.7 percent in 2011 to 30.51 percent in 2021.[48] In 2021, 72,864 patients with ESRD were on the kidney transplant waitlist, of which 27,413 were listed during that year.[49] The IOTA Model will partially focus on the ESRD patients who are on the kidney transplant waitlists of the kidney transplant hospitals that would be required to participate in this Model. ESRD patients represent a small portion of the U.S. population, but the disease burden to the patient and to CMS is great in terms of health outcomes, survival, quality of life, and cost. The ESRD population accounted for 6.1% of total Medicare expenditures in 2020.[50]

Due to wide variability across eligible kidney transplant hospitals, we are unable to estimate the IOTA Model's attributed patient population until the IOTA participants are randomly selected.

c. Benefits of Kidney Transplantation

ESRD, when a person's kidney function has declined to the point of requiring regular dialysis or a transplant for survival, as the person's kidneys are no longer able to perform life-sustaining functions, is the final stage of CKD. ESRD is a uniquely burdensome condition, with uncertain survival and poor quality of life for patients. The higher mortality and substantially greater expenditures and hospitalization rates for ESRD beneficiaries compared to the overall Medicare population suggest the need to explore policy interventions to enhance patients' survival and life experience, as well as to reduce the impact to Medicare. The IOTA Model aims to improve patient outcomes by incentivizing increased access to kidney transplantation across IOTA participants. Access to this lifesaving treatment may delay or avert dialysis, reduce costs to the Medicare program and to patients, and enhance survival and quality of life.

A kidney transplant involves surgically transplanting a kidney from a living or deceased donor to a kidney transplant recipient. The replacement organ is known as a graft. Most kidneys are transplanted alone, as kidneys transplanted along with other organs are very rare.[51] Fewer than 1,000 patients each year receive a simultaneous kidney-pancreas transplant, which is generally conducted for patients who have kidney failure related to type 1 diabetes mellitus.[52] The kidney in such a simultaneous transplant may come from a living or deceased donor, but other organs mostly come from a deceased donor.

About three-quarters of kidney transplants in the U.S. are deceased donor kidney transplants.[53] For deceased donor transplantation, a patient needs to contact a transplant hospital and arrange for an evaluation to assess the feasibility of surgery. The patient's name would then be added to a list of individuals who can receive organ offers. This is known as the kidney transplant hospital's kidney transplant waitlist. Living donation occurs when a living person donates an organ to a family member, friend, or other individual. People unknown to one another sometimes take part in paired exchanges, which allow the switching of recipients based on blood type and other biological factors. The number of deceased donor kidney donations has increased over the past decade, while living donor kidney donation has remained relatively constant, declining in 2020 with the COVID–19 pandemic.[54]

Kidney transplantation is considered the optimal treatment option for most ESRD patients. Although not a cure for kidney disease, a transplant can help a person live longer and improve quality of life. On average, patients experience 14 to 16 years of function from a kidney from a living kidney donor, while few people survive more than a decade on dialysis.[55] According to one source, the majority of deceased donor kidneys are expected to function for about 9 years, with high quality organs lasting longer.[56] A systematic review of studies worldwide finds significantly lower mortality and risk of cardiovascular events associated with kidney transplantation compared with dialysis.[57] Additionally, this review finds that patients who receive transplants experience a better quality of life than treatment with dialysis.[58] The average dialysis patient is admitted to the hospital nearly twice a year, often as a result of infection, and more than 35 percent of dialysis patients who are discharged are re-hospitalized within 30 days of being discharged.[59] Among transplant recipients, there are lower rates of hospitalizations, emergency department visits, and readmissions compared to those still on dialysis.[60] In general, from the standpoint of long-term survival and quality of life, a living donor kidney transplant is considered the best among all kidney transplant options for most people with CKD.[61] [62]

A cost advantage also arises with kidney transplantation. Per-person per-

[46] Strohmaier, S., Wallisch, C., Kammer, M., Geroldinger, A., Heinze, G., Oberbauer, R., & Haller, M.C. (2022). Survival Benefit of First Single-Organ Deceased Donor Kidney Transplantation Compared With Long-term Dialysis Across Ages in Transplant-Eligible Patients With Kidney Failure. *JAMA Network Open, 5*(10), e2234971. *https://doi.org/10.1001/jamanetworkopen.2022.34971*.

[47] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S., & Gill, J. (2011). Systematic Review: Kidney Transplantation Compared With Dialysis in Clinically Relevant Outcomes. *American Journal of Transplantation, 11*(10), 2093–2109. *https://doi.org/10.1111/j.1600-6143.2011.03686.x*.

[48] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 7. Figure 7.16.

[49] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 7. Figures 7.1 and 7.2.

[50] United States Renal Data System. 2022. End Stage Renal Disease: Chapter 9.

[51] According to OPTN data, in 2022, there were 389 kidney-heart transplants in the U.S. 789 kidney-liver transplants, 22 kidney-lung transplants, and 3 kidney-intestine transplants. See *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/*.

[52] Health Resources and Services Administration. (2020). Scientific Registry for Transplant Recipients. *OPTN/SRTR 2020 Annual Data Report: Pancreas. https://srtr.transplant.hrsa.gov/annual_reports/2020/Pancreas.aspx*.

[53] United States Renal Data System. 2022. USRDS Annual Data Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 7: Transplantation. Figure 7.10b.

[54] United States Renal Data System. 2022. USRDS Annual Data Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 7: Transplantation. Figure 7.10b.

[55] *Get the Facts on Kidney Transplantation Before You Start Dialysis—Penn Medicine.* (2019, July 24). *www.pennmedicine.org. https://www.pennmedicine.org/updates/blogs/transplant-update/2019/july/kidney-transplant-facts-before-dialysis*.

[56] Organ Procurement and Transplantation Network. Kidney Donor Profile Index (KDPI) Guide for Clinicians. *https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians/#:~:https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians/*.

[57] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S., & Gill, J. (2011). Systematic Review: Kidney Transplantation Compared With Dialysis in Clinically Relevant Outcomes. *American Journal of Transplantation, 11*(10), 2093–2109. *https://doi.org/10.1111/j.1600-6143.2011.03686.x*.

[58] Ibid.

[59] United States Renal Data System. 2022. USRDS Annual Data Report. 2022. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 5: Hospitalization. Figures 5.1a, 5.9.

[60] United States Renal Data System. 2021. USRDS Annual Data Report. Volume 2. End-Stage Renal Disease (ESRD) in the United States. Chapter 5: Hospitalization, Figures 5.1a, 5.6a, 5.8.

[61] Nemati, E., Einollahi, B., Lesan Pezeshki, M., Porfarziani, V., & Fattahi, M.R. (2014). Does Kidney Transplantation With Deceased or Living Donor Affect Graft Survival? *Nephro-Urology Monthly, 6*(4). *https://doi.org/10.5812/numonthly.12182*.

[62] United States Renal Data System. 2022. USRDS Annual Data Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 7: Hospitalization. Figure 7.20.b.

year Medicare FFS spending for beneficiaries with ESRD with a transplant is less than half that for either hemodialysis or peritoneal dialysis.[63] While the benefits to patient survival and quality of life from living donor kidney transplantation are more pronounced, a recent literature review shows that deceased donor kidney transplantation generally produced better outcomes at a lower cost compared to dialysis, although old age and a high comorbidity load among kidney transplant patients may mitigate this advantage.[64] An earlier study, based on a single hospital, showed rates of hospitalization, a substantial factor in health care costs, to be lower among kidney transplant patients than for those on dialysis.[65]

Despite these positive outcomes associated with kidney transplantation, in 2020, only about 30 percent of prevalent ESRD patients (those with existing ESRD diagnoses) in the U.S. had a functioning kidney transplant, or graft.[66] In 2016, only 2.8 percent of incident ESRD patients (patients newly diagnosed with ESRD) received a preemptive kidney transplant, allowing them to avoid dialysis.[67] These rates are substantially below those of other developed nations. The U.S. was ranked 17th out of 42 reporting countries in kidney transplants per 1,000 dialysis patients in 2020, with 42 transplants per 1,000 dialysis patients in 2020.[68] We seek to test policy approaches aimed at increasing the number of kidney transplants over current levels given these relatively low numbers and the overall benefit to patients from transplantation, as well as the potential savings to Medicare.

d. Kidney Transplant Rates and Unmet Needs

Annually, more than one hundred thousand individuals in the U.S. begin treatment for ESRD.[69] Despite transplantation being widely regarded as the optimal treatment for people with ESRD, as well as being more cost-effective in the long term compared to dialysis, only a minority of people with ESRD (13 percent) are added to the waitlist, and even fewer receive a transplant. To be added to the kidney transplant waitlist, a patient must complete an evaluation at a transplant hospital, and the patient must be found to be a good candidate for a transplant. Nearly 5,000 patients on the national kidney transplant waiting list die each year.[70] [71] [72] These trends have persisted for several decades despite increases in the number of kidney transplants from deceased donors and living donors.

From 1996 to 2019, the number of kidneys made available for transplantation from deceased donors grew steadily, in part because of organs that became available as a result of the opioid epidemic.[73] [74] In 2018 and 2019, the total number of kidney transplants rose steadily as compared to previous years.[75] In 2019, almost one third of patients received a transplant within one year of being placed on the waitlist (32.9 percent), and the rate reached 51.8 percent within 5 years of being placed on the waitlist.[76] The number of kidney transplants increased by 10.2 percent from 2018 to 2019, but fell by 2.7 percent from 2019 to 2020, from 24,511 to 23,853. The reduction was precipitated by a 23.6 percent decline in living donor transplants on account of the COVID–19 pandemic.[77] The overall number of patients with a functioning graft continued its upward trend, reaching 245,846 in 2020, an increase of 2.7 percent from 2019.[78] Nonetheless, these gains in kidney transplantation in the U.S. have fallen far short of the prevailing need among individuals with ESRD or facing the prospect of kidney failure. The number of individuals with ESRD added to the waitlist for a kidney transplant reached a high of 28,533 in 2019, but dropped slightly to 25,136 in 2020, while rising to 27,413 in 2021.[79] At the end of 2021, 72,864 individuals were on the waitlist for a kidney transplant.[80]

The increase in deceased donor kidney transplantation was accompanied by a gradual but steady decline in the number of living donor transplants as compared to patients undergoing dialysis. The total number of living donor transplants per year has risen moderately over the past two decades, from 5,048 in 2000 to 5,241 in 2020, and 5,971 in 2021.[81] [82] With the overall dialysis population growing, the rate of living donor transplants per 100 patient-years on dialysis declined from 1.4 to 0.8 transplants from 2010 to 2020.[83] A report states the proportion of patients undergoing living donor kidney donation to have decreased from 37 percent in 2010 to 29 percent in 2019.[84] A study in 2013 of OPTN data found that the decline in living donation

[63] United States Renal Data System. 2022. USRDS Annual Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 9: Healthcare Expenditures for Persons with ESRD. Figure 9.11.

[64] Fu, R., Sekercioglu, N., Berta, W., & Coyte, P.C. (2020). Cost-effectiveness of Deceased-donor Renal Transplant Versus Dialysis to Treat End-stage Renal Disease. *Transplantation Direct, 6*(2), e522. *https://doi.org/10.1097/txd.0000000000000974.*

[65] Khan, S., Tighiouart, H., Kalra, A., Raman, G., Rohrer, R.J., & Pereira, B.J.G. (2003). Resource utilization among kidney transplant recipients. *Kidney International, 64*(2), 657–664. *https://doi.org/10.1046/j.1523-1755.2003.00102.x.*

[66] United States Renal Data System. *2022 Annual Data Report. Volume 2. End Stage Renal Disease Chapter 7 Transplantation Figure 7.16.*

[67] United States Renal Data System. *2018. Annual Data Report. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. Figure 1.2.* Retrieved from *https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/usrds/prior-data-reports/2018.*

[68] United States Renal Data System. 2022. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 11.17b.

[69] United States Renal Data System. 2022. USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD; 2022.Volume 2: End-stage Renal Disease (ESRD) in the United States, Chapter 1: Incidence, Prevalence, Patient Characteristics.

[70] Scientific Registry of Transplant Recipients. Program Specific Reports. *www.srtr.org.* Retrieved June 15, 2023, from *https://www.srtr.org/reports/program-specific-reports/.*

[71] Penn Medicine News. (2020, December 16). *Too Many Donor Kidneys Are Discarded in U.S. Before Transplantation—Penn Medicine. www.pennmedicine.org. https://www.pennmedicine.org/news/news-releases/2020/december/too-many-donor-kidneys-are-discarded-in-us-before-transplantation.*

[72] United States Renal Data System. 2022 Annual Data Report. Volume 2. End Stage Renal Disease Chapter 7 Transplantation Figure 7.4.

[73] Hariharan, S., Israni, A.K., & Danovitch, G. (2021). Long-Term Survival after Kidney Transplantation. New England Journal of Medicine, 385(8), 729–743. *https://doi.org/10.1056/nejmra2014530.*

[74] Durand, C.M., Bowring, M.G., Thomas, A.G., Kucirka, L.M., Massie, A.B., Cameron, A., Desai, N.M., Sulkowski, M., & Segev, D.L. (2018). The Drug Overdose Epidemic and Deceased-Donor Transplantation in the United States: A National Registry Study. *Annals of Internal Medicine, 168*(10), 702–711. *https://doi.org/10.7326/M17-2451.*

[75] United States Renal Data System. 2021. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.11.

[76] United States Renal Data System. 2021. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.7.

[77] United States Renal Data System. 2022. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.10b.

[78] United States Renal Data System. 2022. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.16.

[79] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.1.

[80] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.2.

[81] United States Renal Data System. 2012. Annual Data Report. Atlas ESRD. Table 7.1.

[82] United States Renal Data System. 2023. Annual Data report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.10a.

[83] United States Renal Data System. 2022. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.10a.

[84] Charnow, J.A. (2021, June 8). *Living Donor Kidney Transplants Declined in the Last Decade.* Renal and Urology News. *https://www.renalandurologynews.com/news/living-donor-kidney-transplantation-decreased-after-2010-united-states-trends/.*

appeared most prominent among men, Black/African Americans, and younger and lower income adults, potentially leading to longer waiting times for transplantation, greater dialysis exposure, higher death rates on the waitlist, lower graft and patient survival for recipients, and higher overall healthcare costs for the care of patients with ESRD.[85]

e. Disparities

Kidney transplantation research in the U.S. reveals disparities across a number of different axes including geography, race and ethnicity, disability, socioeconomic status, neighborhood factors, and availability of health insurance.[86] [87] [88] [89] [90] A 2020 study showed substantial disparities in kidney transplant rates among transplant programs at a national level, as well as both among and within donation service areas (DSAs).[91] [92] This study examined data from a registry that included all U.S. adult kidney transplant candidates added to the waitlist in 2011 and 2015, comprising 32,745 and 34,728 individuals, respectively.[93] Among transplant programs nationwide, in 2015, the study found that the probability of a deceased donor transplant within three years for the average patient to be up to 16 times greater in some transplant hospitals as compared to others.[94] Substantial differences in probability of deceased donor transplantation were found even within DSAs, where all transplant programs utilize the same OPO and local organ supply. For the 2015 cohort, there was a median 2.3-fold difference between the highest and lowest hospital in each DSA in the 43 of 58 DSAs with more than one transplant hospital. The largest absolute difference in probability of transplant occurred in a DSA with seven transplant programs, with a patient on the waitlist at the transplant program with the highest probability of transplant being 9.8 times more likely to receive a transplant than a patient at the transplant program with the lowest probability of receiving a transplant.[95] Factors such as local organ supply, the characteristics of individuals on the waitlist of a given transplant program, the size of the waitlist, and the transplant program's volume of transplants may account for the differences observed nationally across DSAs. However, the variation among transplant programs across DSAs is significantly associated with organ offer acceptance patterns at individual transplant hospitals.[96] This underscores the need to address geographic disparities and for more transparency on how transplant programs make decisions on organ offers for their waitlist patients.

Living donor kidney donation also varies widely among transplant hospitals. A 2018 report using OPTN data from 2015 showed that while most transplant hospitals perform few living donor kidney transplants, certain transplant hospitals have substantially higher rates for their waitlist patients than the median rate. Differences among transplant hospitals were correlated with geographic region and the number of deceased donor kidney transplantations performed.[97] This underscores the need for initiatives and processes among transplant hospitals to encourage living donations to reduce geographic disparities.

Disparities in kidney transplantation rates for various populations in the U.S. have long been documented. Literature over the past two decades has focused on Non-Hispanic Black patients, who experience lower rates of deceased and living donor kidney transplantation as compared to Non-Hispanic White patients, while being four times more likely to have kidney failure. Black/African Americans and Hispanics/Latinos with kidney failure experience lower rates of kidney transplantation compared with White patients.[98] Additionally, Black/African Americans and Hispanics/Latinos, along with Asians, American Indian/Alaskan Natives, and other minorities, are at a higher risk of illnesses that may eventually lead to kidney failure, such as diabetes and high blood pressure.[99]

The literature over several decades has also addressed the effect of differences in age, gender, socioeconomic status (SES), and cultural aspects.[100] Recent studies have emphasized poverty and income differentials in analyzing the interplay of these and other factors among populations referred for kidney transplantation at several large transplant hospitals.[101] [102] [103] [104] This

[85] Rodrigue, J.R., Schold, J.D., & Mandelbrot, D.A. (2013). The Decline in Living Kidney Donation in the United States. *Transplantation Journal, 96*(9), 767–773. *https://doi.org/10.1097/tp.0b013e318298fa61*.

[86] 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*.

[87] Melanson T., Basu M., Plantiga L., Pastan S., Mohan S., Patzer R. (2017). Variation in Living Donor Kidney Transplantation among U.S. Transplant Centers. *American Journal of Transplantation, 17* (suppl 3).

[88] United States Renal Data System. 2022. Annual Data Report. Supplements: COVID–19, Racial and Ethnic Disparities Figures 14.14 and 14.15.

[89] Wesselman, H., Ford, C.G., Leyva, Y., Li, X., Chang, C.-C.H., Dew, M.A., Kendall, K., Croswell, E., Pleis, J.R., Ng, Y.H., Unruh, M.L., Shapiro, R., & Myaskovsky, L. (2021). Social Determinants of Health and Race Disparities in Kidney Transplant. *Clinical Journal of the American Society of Nephrology, 16*(2), 262–274. *https://doi.org/10.2215/cjn.04860420*.

[90] Ng, Y.-H., Pankratz, V.S., Leyva, Y., Ford, C.G., Pleis, J.R., Kendall, K., Croswell, E., Dew, M.A., Shapiro, R., Switzer, G.E., Unruh, M.L., & Myaskovsky, L. (2019). Does Racial Disparity in Kidney Transplant Wait-listing Persist After Accounting for Social Determinants of Health? *Transplantation,* 1. *https://doi.org/10.1097/tp.0000000000003002*.

[91] With the enactment of NOTA, CMS designated DSAs; generally, each DSA includes an OPO within its geographic area. Until March 2021, when OPTN implemented the current policy for allocation of deceased donor kidneys, the priority for organs acquired by an OPO was based, among other factors, on an individual's residence within the DSA extending around the OPO.

[92] 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*.

[93] King et al. 2020. 2900.

[94] King et al. 2020. 2903.

[95] King et al., 2020. 2903.

[96] King et al. 2020. 2903–2904.

[97] Melanson T., Basu M., Plantiga L., Pastan S., Mohan S., Patzer R. (2017). Variation in Living Donor Kidney Transplantation among U.S. Transplant Centers. *American Journal of Transplantation, 17* (suppl 3).

[98] United States Renal Data System. 2022. Annual Data Report. Supplements: COVID–19, Racial and Ethnic Disparities Figures 14.14 and 14.15.

[99] National Kidney Foundation. (2016, January 7). Race, Ethnicity, & Kidney Disease. National Kidney Foundation. *https://www.kidney.org/atoz/content/minorities-KD*.

[100] Patzer, R.E., & Pastan, S.O. (2020). Policies to promote timely referral for kidney transplantation. *Seminars in Dialysis, 33*(1), 58–67. *https://doi.org/10.1111/sdi.12860*.

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

[102] Wesselman, H., Ford, C.G., Leyva, Y., Li, X., Chang, C.-C.H., Dew, M.A., Kendall, K., Croswell, E., Pleis, J.R., Ng, Y.H., Unruh, M.L., Shapiro, R., & Myaskovsky, L. (2021). Social Determinants of Health and Race Disparities in Kidney Transplant. *Clinical Journal of the American Society of Nephrology, 16*(2), 262–274. *https://doi.org/10.2215/cjn.04860420*.

[103] Ng, Y.-H., Pankratz, V.S., Leyva, Y., Ford, C.G., Pleis, J.R., Kendall, K., Croswell, E., Dew, M.A., Shapiro, R., Switzer, G.E., Unruh, M.L., & Myaskovsky, L. (2019). Does Racial Disparity in Kidney Transplant Wait-listing Persist After Accounting for Social Determinants of Health? *Transplantation,* 1. *https://doi.org/10.1097/tp.0000000000003002*.

[104] Schold, J.D., Gregg, J.A., Harman, J.S., Hall, A.G., Patton, P.R., & Meier-Kriesche, H.-U. (2011). Barriers to Evaluation and Wait Listing for Kidney

research extends in time prior to the Kidney Allocation System (KAS) of 2014, which aimed to lessen the impact of racial differences on access to kidney transplantation.

Research findings support the proposition that a broad interpretation of social determinants of health (SDOH) may substantially explain racial disparities in both deceased and living donor kidney transplantation.[105] Recently, a comprehensive survey of the literature on disparities in transplantation for kidneys and other organs found that socioeconomic factors may substantially explain disproportionately lower transplant rates and longer wait times.[106] As described in recent literature, a person's SDOH may contribute to inequities in their prospects for waitlist registration and receipt of transplantation.[107] [108] [109] SDOH is defined more broadly than socioeconomic status, to include those conditions in the places where people live, learn, work, and play that affect a wide range of health and quality of life risks and outcomes.[110] More specifically, SDOH include variations in employment, neighborhood factors, education, social support systems, and healthcare coverage that impact health outcomes.

A salient group of recent analyses focused on a cohort of patients initially referred for evaluation for a kidney transplant at a large urban transplant hospital between 2010 and 2012. These studies showed lower waitlist registration and transplant rates for Black/African Americans, regardless of SDOH.[111] [112] One of the studies reports that racial difference showed a weaker association with the rate of waitlist registration after the introduction of the KAS. Another of these studies, focusing on transplant rates as the outcome, showed that even after accounting for social determinants of health, Black patients had a lower likelihood of kidney transplant and living-donor transplant, but not deceased-donor transplant. Black race, older age, lower income, public insurance, more comorbidities, being transplanted before changes to the KAS, greater religiosity, less social support, less transplant knowledge, and fewer learning activities were each associated with a lower probability of any kidney transplant.[113] Similarly, an earlier study of a population at a single transplant hospital found that income and insurance attenuated the association between racial difference and placement on the waitlist for a kidney transplant.[114] The findings in these studies of the enduring influence of cultural, socioeconomic and demographic factors apart from racial difference underscore the need to consider initiatives and improvement activities aimed at addressing SDOH for ESRD patients to remove barriers to access to kidney transplantations.

Living donor transplantation has demonstrated the enduring influence of racial disparities, but also the importance of SES and neighborhood factors. The cohort of patients identified previously, initially referred for evaluation at a large urban hospital between 2010 and 2012, showed that for living donor transplantation, Black/African American race and lower income held a stronger association with a lower probability of living donor transplant than with deceased donor donation.[115] These results accord with findings nationwide that White patients are more likely to receive a living donor transplant, followed by Asian and Hispanic/Latino patients. Black/African American patients have had lower rates of living donor transplants than other racial or ethnic groups.[116] Explanations for these differences have included disparate rates of diabetes, obesity, and hypertension observed among minority populations that may contraindicate living donation by a relative; cultural differences in willingness to donate or ask for a living donation; concerns about costs among potential donors; and lack of knowledge about living donor transplantation on the part of patients, their families, and health care providers.[117] [118]

Research over several decades confirms the relation between health care access and SES factors and disparities in living donor kidney transplantation receipt for Black/African American and Hispanic/Latino patients, and, additionally, that these disparities have increased over time.[119] [120] [121] [122] According to one study, between 1995 and 2014, disparities in the receipt of living donor kidney transplantation grew more for Black/African Americans and Hispanics/Latinos: (1) living in poorer (versus wealthier) neighborhoods; (2) without (versus with) a college degree; and (3) with Medicare (versus private insurance).[123] The study suggests that delays in the receipt of kidney care may contribute to reported racial and ethnic differences in the quality and timing of discussions among patients, families, and clinicians about living donor kidney transplantation as a treatment option.[124]

One study also established associations between rates of living donor kidney transplantation for Black/African Americans and transplant hospital characteristics. While recognizing the potential effect of clinical factors, the study found that hospitals with high overall rates of living donor kidney transplantation

Transplantation. *Clinical Journal of the American Society of Nephrology, 6*(7), 1760–1767. *https://doi.org/10.2215/cjn.08620910.*

[105] Reed, R.D., & Locke, J.E. (2020). Social Determinants of Health: Going Beyond the Basics to Explore Racial Disparities in Kidney Transplantation. *Transplantation, 104,* 1324–1325.(7), 1324–1325.–1325. *https://doi.org/10.1097/TP.0000000000003003.*

[106] National Academies of Sciences, Engineering, and Medicine. (2022). *Realizing the Promise of Equity in the Organ Transplantation System* (K.W. Kizer, R.A. English, & M. Hackmann, Eds.; pp. 88–93). National Academies Press. *https://doi.org/10.17226/26364.*

[107] Centers for Disease Control and Prevention. *Social Determinants of Health at CDC.* Retrieved June 13, 2023, from *https://www.cdc.gov/about/priorities/social-determinants-of-health-at-cdc.html?CDC_AAref_Val=https://www.cdc.gov/about/sdoh/index.html.*

[108] Wesselman et al, 2021.

[109] Ng et al, 2020.

[110] Centers for Disease Control and Prevention. *Social Determinants of Health at CDC.* Retrieved June 13, 2023, from *https://www.cdc.gov/about/priorities/social-determinants-of-health-at-cdc.html?CDC_AAref_Val=https://www.cdc.gov/about/sdoh/index.html.*

[111] Ng Y et al. 2020. 1453.

[112] Wesselman et al, 2021. 271.

[113] Wesselman et al. 2021. 262.

[114] Schold et al, 2021.

[115] Wesselman et al, 2021. 270.

[116] United States Renal Data System. 2022. Annual Data Report. End Stage Renal Disease Chapter 7 Transplantation Figure 7.10a.

[117] Purnell, T.S., Hall, Y.N., & Boulware, L.E. (2012). Understanding and Overcoming Barriers to Living Kidney Donation Among Racial and Ethnic Minorities in the United States. *Advances in Chronic Kidney Disease, 19*(4), 244–251. *https://doi.org/10.1053/j.ackd.2012.01.008.*

[118] Rodrigue, J.R., Kazley, A.S., Mandelbrot, D.A., Hays, R., LaPointe Rudow, D., & Baliga, P. (2015). Living Donor Kidney Transplantation: Overcoming Disparities in Live Kidney Donation in the US—Recommendations from a Consensus Conference. *Clinical Journal of the American Society of Nephrology, 10*(9), 1687–1695. *https://doi.org/10.2215/cjn.00700115.*

[119] Purnell, T.S., Luo, X., Cooper, L.A., Massie, A.B., Kucirka, L.M., Henderson, M.L., Gordon, E.J., Crews, D.C., Boulware, L.E., & Segev, D.L. (2018). Association of Race and Ethnicity With Live Donor Kidney Transplantation in the United States From 1995 to 2014. *JAMA, 319*(1), 49. *https://doi.org/10.1001/jama.2017.19152.*

[120] Hall, E.C., James, N.T., Garonzik Wang, J.M., Berger, J.C., Montgomery, R.A., Dagher, N.N., Desai, N.M., & Segev, D.L. (2012). Center-Level Factors and Racial Disparities in Living Donor Kidney Transplantation. *American Journal of Kidney Diseases, 59*(6), 849–857. *https://doi.org/10.1053/j.ajkd.2011.12.021.*

[121] Gore, J.L., Danovitch, G.M., Litwin, M.S., Pham, P–T.T., & Singer, J.S. (2009). Disparities in the Utilization of Live Donor Renal Transplantation. *American Journal of Transplantation, 9*(5), 1124–1133. *https://doi.org/10.1111/j.1600-6143.2009.02620.x.*

[122] Rodrigue et al. 2015.

[123] Purnell et al. 2015. 58.

[124] Purnell et al. 2015. 59.

showed significantly decreased racial disparities. The authors suggest that such high rates reveal commitment to living donor kidney transplantation, possibly shown in better education programs, more formalized procedures to reduce failure to complete transplant evaluations, increased use of medically complex and unrelated donors, and more success in reducing financial barriers to living donor kidney donation.[125] The study also notes that hospitals with higher percentages of Black/African American candidates experience greater racial disparities. The authors surmise that such a high percentage might indicate an urban setting exhibiting greater differences in access to health care between Black/African Americans and other populations.[126]

Studies have also shown discrimination on the basis of disability with regard to organ transplantation, particularly for individuals with intellectual and developmental disabilities, who are often assumed by transplant providers to be unable to manage post-transplantation care requirements.[127] Discrimination occurs even though individuals' disabilities that are not related to the need for an organ transplant generally have little or no impact on the likelihood that the transplant would be successful.[128] The American Society of Transplant Surgeons has recommended that no patient be discriminated against or precluded from transplant listing solely due to the presence of a disability, whether physical or psychological.[129]

CMS kept these concerns in mind when developing the IOTA Model proposals. The IOTA Model uses performance-based payments that hold transplant hospitals selected as the IOTA participants financially accountable for improvements in access to both deceased and living donor kidney transplantations. To reduce disparities and promote health equity, CMS proposed that the IOTA participants would be required to develop and submit a Health Equity Plan to CMS. This model design feature is aimed at encouraging IOTA participants to reassess their processes and policies around living and deceased donor kidneys and promote investments in performance and quality improvement activities that address barriers to care, including SDOH. The sequence of steps that patients need to undertake to gain access to kidney transplantation is complex, and the challenge posed by this process for potential recipients may be compounded by racial, socioeconomic and neighborhood factors.

f. Post-Transplant Outcomes

While the need for kidney transplants has grown, the rates of patient and graft survival have increased. Between 2001 and 2020, graft survival rates at 1 and 5 years showed an increasing trend.[130] Patient survival at 1 year increased from 97.5 percent in 2001 to 99.2 percent in 2018, but then declined to 98.9 percent in 2019 and 98.4 percent in 2020; patient survival at 5 years rose from 89.8 percent in 2001 to an all-time high of 93.6 percent in 2013, dropping slightly to 93.2 percent in 2016.[131] For living donor kidney transplants, the rate of graft failure at 3 years decreased from 3.0 per 100 person years in 2010 to 2.1 per 100 person years in 2018. The rate of death at 3 years with a functioning graft also decreased from 1.2 to 1.0 per 100 person-years.[132] For deceased donor kidney transplants, the rate of graft failure at 3 years decreased from 2010 (6.3 per 100 patient years) to 2014 (4.9 per 100 patient years), but increased to 5.3 per 100 patient years in 2018. The same pattern was observed for death with a functioning graft, except that the rate in the 2018 cohort (2.8 per 100 patient years) exceeded that of the 2010 cohort (2.6 per 100 patient years).[133]

A study published in the New England Journal of Medicine in 2021 shows the advantage of transplantation using deceased donor organs over long-term dialysis, even with an increasing trend of adverse conditions among recipients and donors. Notably, patient survival improved between the 1990s and the period from 2008 to 2011, despite increases in both (a) recipients' age, body-mass index (BMI), frequency of diabetes, and length of time undergoing dialysis, as well as a higher proportion of recipients with a previous kidney transplant; and (b) donors' age and in the percentage of donations after circulatory death.[134] Early referral of patients for transplants, kidney exchange programs, better diagnostic tools to identify early acute rejection, innovative therapies for countering rejection and infection, and optimization of immunosuppressive medications may be opportunities to enhance kidney graft survival.[135]

g. Non-Acceptance and Discards in Kidney Transplantation

Studies have documented the substantial extent of deceased donor kidney non-utilization in the U.S. relative to other countries (although methods of defining these rates differ among countries), as well as a steady increase in that trend over the past two decades.[136] [137] [138] [139] [140] A study in 2018 described donor-specific factors, such as biopsy findings and donor history, along with an increasing selectivity among transplant hospitals in accepting organs for transplant and inability to locate a recipient as contributing to this increase

[125] Hall et al. 2012. 855.

[126] Hall et al. 2012. 855.

[127] *See, for example,* National Council on Disability. (2019). *Organ Transplant Discrimination Against People with Disabilities: Part of the Bioethics and Disability Series. https://www.ncd.gov/report/organ-transplant-discrimination-against-people-with-disabilities.*

[128] *Id.* at 38–40.

[129] Am. Soc'y of Transplant Surgeons, *Statement Concerning Eligibility for Solid Organ Transplant Candidacy* (Feb. 12, 2021), *https://asts.org/advocacy/position-statements.https://asts.org/advocacy/position-statements.*

[130] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Transplantation. Figures 7.19a and 7.19b.

[131] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figures 7.20a and 7.20b.

[132] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.21a.

[133] United States Renal Data System. 2023. Annual Data Report Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.21b.

[134] Hariharan, S., Israni, A.K., & Danovitch, G. (2021). Long-Term Survival after Kidney Transplantation. *New England Journal of Medicine, 385*(8), 729–743. *https://doi.org/10.1056/nejmra2014530.*

[135] Hariharan, S., Israni, A.K., & Danovitch, G. (2021). Long-Term Survival after Kidney Transplantation. *New England Journal of Medicine, 385*(8), 729–743. *https://doi.org/10.1056/nejmra2014530.*

[136] Mohan, S., Chiles, M.C., Patzer, R.E., Pastan, S.O., Husain, S.A., Carpenter, D.J., Dube, G.K., Crew, R.J., Ratner, L.E., & Cohen, D.J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International, 94*(1), 187–198. *https://doi.org/10.1016/j.kint.2018.02.016.*

[137] Aubert, O. Reese. P. Audry, B. Bouatou, B. Raynaud, M. Viglietti, D. Legendre, C. Glotz, D. Empana, J. Jouben, X. Lefaucheur, C. Jacquelinet, C. Loupy, A. (2019). Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased US Acceptance. *JAMA Internal Medicine, 179*(10), 1365–1374. *https://doi.org/10.1001/jamainternmed.2019.2322.*

[138] Ibrahim, M., Vece, G., Mehew, J., Johnson, R., Forsythe, J., Klassen, D., Callaghan, C., & Stewart, D. (2019). An international comparison of deceased donor kidney utilization: What can the United States and the United Kingdom learn from each other? *American Journal of Transplantation, 20*(5), 1309–1322. *https://doi.org/10.1111/ajt.15719.*

[139] Stewart, D.E., Garcia, V.C., Rosendale, J.D., Klassen, D.K., & Carrico, B.J. (2017). Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. *Transplantation, 101*(3), 575–587. *https://doi.org/10.1097/tp.0000000000001539.*

[140] Health Resources and Services Administration. OPTN. (2017). *Two year analysis shows effects of kidney transplantation system.* Optn. *transplant.hrsa.gov.* Retrieved May 30, 2023, from *https://optn.transplant.hrsa.gov/news/two-year-analysis-shows-effects-of-kidney-allocation-system/.*

in non-utilization.[141] Within the context of the COVID–19 pandemic, the non-utilization of deceased donor kidneys in 2020 rose to the highest level up to that time, 21.3 percent, despite the decline in discard of organs from hepatitis C-positive donors.[142] [143] According to one analysis, the deceased donor kidney discard rate peaked at 27 percent during the fourth quarter of 2021.[144]

Since the KAS went into effect in 2014, the OPTN has aimed to address the high rate of kidneys going unused. The new kidney allocation system was developed in response to higher than necessary discard rates of kidneys, variability in access to transplants for candidates who are harder to match due to biologic reasons, inequities resulting from the way waiting time was calculated, and a matching system that results in unrealized life years and high re-transplant rates.[145] The KAS also revised the system that matched waitlisted individuals with available organs.[146] As part of the KAS, the Kidney Donor Profile Index (KDPI) was implemented to assess the quality of kidneys procured for kidney transplants. The KDPI is based on a preliminary measurement, the Kidney Donor Risk Index (KDRI), which estimates the relative risk of post-transplant kidney graft failure based on scores for the deceased donor on a set of 10 demographic and clinic characteristics, including age, height, weight, ethnicity, history of hypertension, history of diabetes, cause of death, serum creatinine, hepatitis C virus status, and donation after circulatory death status.[147] This relative risk is determined in relation to the overall distribution of a grouping of these scores across the overall deceased donor population for the previous year. The KDPI transforms the KDRI to a zero-to-100 scale. Lower KDPI scores are associated with greater expected post-transplant longevity, while higher KDPI scores are associated with a worse expected outcome in this regard.[148]

According to these new allocation rules, the KDPI of an available organ was to be assessed, with donor kidneys with low KDPI scores being offered to patients scoring high in terms of expected longevity. New revisions to the KAS also included an individual's time on dialysis prior to waitlisting to assess waiting time used for determining priority for an available organ, and new rules that allowed for greater access for candidates with blood type B to donor kidneys with other blood types.[149]

An OPTN data analysis from 2014 to 2016, the first two years after KAS implementation, showed that despite substantial increases in both deceased kidney donor transplants and deceased kidney donation, the kidney discard rate increased to 19.9 percent in 2016.[150] The OPTN linked the discard rates to KDPI scores, with fewer than 3 percent of donor kidneys with KDPI between zero and 20 percent discarded, compared with 60 percent of donor kidneys with KDPI between 86 and 100 percent being discarded.[151]

In March 2021, OPTN finalized a newer allocation policy, which eliminated the use of DSAs and regions from kidney and pancreas donor distribution. These measures were part of a framework announced in 2019 that also applied to heart, lung, and liver donor distribution, with the goal of reducing the importance of geography in patients' access to organs, and, instead, emphasizing medical urgency.[152] [153] The new system instituted a point system with up to 2 points (equal to 2 years on the wait list) for patients listed at transplant hospitals within 250 nautical miles of the donor hospital, and the points decreasing linearly from the donor hospital to the circle perimeter. The more points an individual has, the higher their position on the waitlist and the more likely they are to receive an organ offer. If there is no candidate within the designated radius, the kidney is offered to patients listed at hospitals outside the fixed circle, based on separate proximity points that decrease linearly as the location of a patient approaches 2,500 nautical miles from the donor hospital.[154]

Interested parties within the transplant ecosystem commented that the new policy might further contribute to the increasing rate of donor organ non-acceptance. According to one review, sharing kidneys over a broader geographic region means that OPOs would need to work with transplant hospitals with which there was no prior relationship.[155] Concern was also expressed about increased transportation time and procurement costs, risk associated with air transport, and a greater number of interactions between transplant hospitals and OPOs.[156] [157] [158] One study notes that policymakers would need to assess the extent to which the new kidney allocation policy might affect organ offer acceptance patterns, organ recovery and utilization rates, and wait times both for the transplant hospital and broader

[141] Mohan, Chiles et al. (2018).

[142] Lentine, K. Smith, J. Hart, A. Miller, J. Skeans, M. Larkin, L. Robinson, A. Gauntt, K. Israni, A. Hirose, R. Snyder, J. (2022). OPTN/SRTR 2020 Annual Data Report: Kidney. American Journal of Transplantation 22(Suppl 2) 21–136.

[143] Following the introduction of certain anti-viral drugs, transplanting kidneys from donors infected with Hepatitis C has shown promising outcomes in recent studies. See Penn Medicine News ''Penn Researchers Continue to Advance Transplantation of Hepatitis C Virus-infected kidneys into HCV-Negative Recipients'' August 31, 2020 *https://www.pennmedicine.org/news/news-releases/2020/august/penn-researchers-advance-transplantation-hepatitis-c-virus-infected-kidneys-hcv-negative-recipients.*

[144] Cron, D. Husain, S. Adler, J. (2022). The new distance-based kidney allocation system: Implications for patients, transplant centers, and Organ Procurement Organizations. *Current Transplantation Reports, 9*(4), 304. *https://doi.org/10.1007/s40472-022-00384-z.*

[145] OPTN Kidney Transplantation Committee. (n.d.). *The New Kidney Allocation System (KAS) Frequently Asked Questions.* Retrieved December 6, 2023, from *https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* p. 4.

[146] OPTN. (n.d.) *The New Kidney Allocation System (KAS) Frequently Asked Questions. https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* p. 4.

[147] OPTN. (n.d.). *The New Kidney Allocation System Frequently Asked Questions. https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* pp. 8–9.

[148] OPTN. (n.d.). *The New Kidney Allocation System Frequently Asked Questions . https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* p. 4.

[149] OPTN. (n.d.). *The New Kidney Allocation System Frequently Asked Questions. https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* p. 4.

[150] OPTN. (2017, July 9). *Two Year Analysis shows effects of Kidney Allocation System.* Retrieved June 9, 2023, from *https://optn.transplant.hrsa.gov/news/two-year-analysis-shows-effects-of-kidney-allocation-system/.*

[151] OPTN. (2017, July 9). *Two Year Analysis shows effects of Kidney Allocation System.* Retrieved June 9, 2023, from *https://optn.transplant.hrsa.gov/news/two-year-analysis-shows-effects-of-kidney-allocation-system/.*

[152] Potluri, V.S., & Bloom, R.D. (2021). Effect of Policy on Geographic Inequities in Kidney Transplantation. *American Journal of Kidney Diseases, 79*(6), 897–900. *https://doi.org/10.1053/j.ajkd.2021.11.005.*

[153] Penn Medicine. (2021, November 17). Update: Change in Organ Allocation Designed to Increase Equity in US Kidney and Pancreas Transplantation. *Penn Medicine Physician Blog. https://www.pennmedicine.org/updates/blogs/penn-physician-blog/2021/november/change-in-organ-allocation-designed-to-increase-equity-in-us-kidney-and-pancreas-transplantation.*

[154] Potluri, Bloom. (2021). 897–898.

[155] Potluri, Bloom. (2021) 898.

[156] Gentry, S.E., Chow, E.K.H., Wickliffe, C.E., Massie, A.B., Leighton, T., & Segev, D.L. (2014). Impact of broader sharing on the transport time for deceased donor livers. *Liver Transplantation, 20*(10), 1237–1243. *https://doi.org/10.1002/lt.23942.*

[157] Chow, E.M., DiBrito, S.R., Luo, X., Wickliffe, C., Massie, A.B., Locke, J.E., Gentry, S.E., Garonzik-Wang, J., & Segev, D.L. (2018). Long Cold Ischemia Times in Same Hospital Deceased Donor Transplants. *Transplantation, 102*(3), 471–477. *https://doi.org/10.1097/tp.0000000000001957.*

[158] Adler, J.T., Husain, S.A., King, K.L., & Mohan, S. (2021). Greater complexity and monitoring of the new Kidney Allocation System: Implications and unintended consequences of concentric circle kidney allocation on network complexity. *American Journal of Transplantation, 21*(6), 2007–2013. *https://doi.org/10.1111/ajt.16441.*

geographic areas.[159] Another report cited unpublished SRTR data, saying that preliminary results suggest an increase in the transplant rate overall, but a trend toward higher donor kidney discard and increased cold ischemia time.[160]

A similar study assessing deceased donor kidney discards from 2000 to 2015 found that 17.3 percent of 212,305 procured deceased donor kidneys were discarded, representing a 91.5 percent increase in deceased donor kidney discards during the same time period. The increase in donor kidney discards outpaced the number of organs recovered for transplantation, adversely impacting transplantation rates and waitlist times. Kidneys with higher KDPIs and from donors with more disadvantageous characteristics were more likely to be discarded. The estimated 5-year graft survival for even the lowest quality kidneys substantially exceeds the average 5-year dialysis survival rate, making discard patterns concerning.[161] The study indicates a significant overlap in the quality of discarded and transplanted deceased donor kidneys, and substantial geographical variation in the odds of donor kidney discards, which, as seen previously, would continue to be observed in SRTR data for following years.[162] The study also found patterns that indicate factors beyond organ quality, including biopsy findings, donor history and poor organ function, and inability to locate a kidney donor recipient, may factor into deceased organ acceptance decisions. Other factors may be driving the deceased donor organ discard rates, as the study found that ''discarded organs were more likely to come from older, heavier donors who were Black, female, diabetic, hypertensive, with undesirable social behavior and higher terminal creatinine.'' [163] This finding accords with observed discard patterns from earlier studies whereby recipients of marginal kidneys, in terms of advanced donor age, hypertension, diabetes, or greater cold ischemia time, showed lower mortality and greater survival benefit for many candidates as compared to staying on the transplant wait list.[164] [165] [166]

Research at this time suggests that CMS regulatory requirements and OPTN policies may have been contributing to transplant hospitals growing more selective in choosing organs for their waitlisted patients. A study from 2017 examined OPTN registry data for deceased donors from 1987 to 2015, showing that changes in the donor pool and certain clinical practices explained about 80 percent of the increase in non-utilization of deceased donor kidneys.[167] However, according to the study, the remainder of kidney discards, not accounted for by these factors, suggests that increased risk aversion was leading transplant hospitals to be more selective about the kidneys they accept, regardless of the actual risk profile. Furthermore, increasing reliance on the part of OPTN, CMS, and private insurers on program-specific reports that assessed the performance of transplant hospitals on transplant graft and recipient survival rates might have been contributing to the overall trend of organs going unused.[168]

The finding of high rates of non-use of organs that could potentially be transplanted with positive outcomes has led to closer examination of trends among transplant hospitals in declining the possible use of organs for specific patients. Information on each organ that is recovered by an OPO is shared with the OPTN, which runs the matching system that determines which organ should be offered to which recipient. If an organ is determined to be a good match for a particular patient, then the OPTN would offer that organ to the transplant hospital at which the patient is waitlisted on the patient's behalf.[169] A transplant hospital can decline an offer without informing the candidate of the offer or the reason it was declined.[170] A study in 2019 focused on patient outcomes associated with declines in offers of organs by transplant hospitals. Using OPTN data, the study identified a cohort of 280,041 adults on the kidney transplant waitlist (out of 367,405 candidates on the waitlist from 2008 through 2015, the study period) who received one or more offers for a deceased donor kidney during that period. More than 80 percent of deceased donor kidneys were declined on behalf of one or more candidates before being accepted for transplant, and a mean of 10 candidates who previously received an offer died every day during the study period.[171] As reported by transplant hospitals, organ or donor quality concerns accounted for 92.6 percent of all declined offers, whereas 2.6 percent of offers were refused because of patient-related factors, and an even smaller number for logistical limitations or other concerns. While organ or donor quality concerns remained the primary reason for declined offers across all KDPI ranges, the study observed marked State-level variability in the interval between first offer and death or transplant and in the likelihood of dying while having remained on the wait list after receiving an offer.[172]

The methodology and findings of this study are notable since they draw a correlation between the specific patterns among transplant hospitals of organ non-acceptance and the longevity of patients on the wait list. The tendency among certain hospitals to choose to not use kidneys for specific patients is shown apart from the distinct finding of organs going unused and being discarded. The study shows the potential for a similar effect on patient survival from organ offer non-acceptance as for organ non-use. The authors of an earlier study commented that low acceptance rates of organ offers lead to inefficiency, longer ischemia time, unequal access to donated kidneys, and perhaps to higher rates of discarded organs.[173] The findings in the

[159] Adler et al., 2021. 2012.

[160] Cron, D.C., S. Ali Husain, & Adler, J.T. (2022). The New Distance-Based Kidney Allocation System: Implications for Patients, Transplant Centers, and Organ Procurement Organizations. *Current Transplantation Reports, 9*(4), 302–307. *https://doi.org/10.1007/s40472-022-00384-z.*

[161] Mohan, Chiles et al. 2018. p. 192.

[162] Mohan et al. 2018. p. 195.

[163] Mohan et al. 2018. 192.

[164] Ojo, A.O., Hanson, J.A., Herwig Ulf Meier-Kriesche, Chike Nathan Okechukwu, Wolfe, R.R., Leichtman, A.B., Agodoa, L.Y., Kaplan, B., & Port, F.K. (2001). Survival in Recipients of Marginal Cadaveric Donor Kidneys Compared with Other Recipients and Wait-Listed Transplant Candidates. *Journal of the American Society of Nephrology, 12*(3), 589–597. *https://doi.org/10.1681/asn.v123589.*

[165] Massie, A.B., Luo, X., Chow, E.K.H., Alejo, J.L., Desai, N.M., & Segev, D.L. (2014). Survival Benefit of Primary Deceased Donor Transplantation With High-KDPI Kidneys. *American Journal of Transplantation, 14*(10), 2310–2316. *https://doi.org/10.1111/ajt.12830.*

[166] Cohen, J.B., Eddinger, K.C., Locke, J.E., Forde, K.A., Reese, P.P., & Sawinski, D. (2017). Survival Benefit of Transplantation with a Deceased Diabetic Donor Kidney Compared with Remaining on the Waitlist. *Clinical Journal of the American Society of Nephrology, 12*(6), 974–982. *https://doi.org/10.2215/cjn.10280916.*

[167] Stewart et al. (2017). 575.

[168] Stewart et al. (2017). 585.

[169] National kidney Foundation. (2017, February 10). *The Kidney Transplant Waitlist—What You Need to Know.* National Kidney Foundation. *https://www.kidney.org/atoz/content/transplant-waitlist.*

[170] Husain, S.A., King, K.L., Pastan, S., Patzer, R.E., Cohen, D.J., Radhakrishnan, J., & Mohan, S. (2019). Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Network Open, 2*(8), e1910312. *https://doi.org/10.1001/jamanetworkopen.2019.10312.*

[171] Husain et al. 2019.

[172] Husain et al. 2019.

[173] Wolfe, R.A., Laporte, F., Rodgers, A.M., Roys, E., Fant, G., & Leichtman, A.B. (2007). Developing Organ Offer and Acceptance Measures: When

2019 study of a wide range of organ offer acceptance rates among transplant hospitals nationwide, as well as of the relation between organ offer declines and patient deaths, suggest the need for incentives for transplant hospitals to accept earlier offers for their patients, which, in turn, could reduce cold ischemia time, and, on the whole, increase patient survival.

h. Non-Acceptance and Discards in Transplantation for Other Solid Organ Types

SRTR has also tracked the non-use, or discard rate, of other solid organ types. In 2020, 9.5 percent of livers recovered were not transplanted, with livers from older donors less likely to be transplanted.[174] The discard rate for pancreases was 23.4 percent in 2020; organs from obese donors were highly likely not to be transplanted.[175] The discard rate for hearts in 2020 was one percent, having stayed similar over the previous decade.[176]

Liver transplantation shows survival benefits for individuals with chronic liver disease, but liver transplantation suffers from a severe shortage of donor organs.[177] [178] A study from 2012 shows organ offer non-acceptance patterns on the part of transplant programs affect mortality for individuals with end-stage liver disease in a similar manner as for ESRD patients. According to the study, most candidates for a liver transplant who died or were removed from the wait list had received at least one organ offer, suggesting that a substantial portion of waitlist mortality results in part from declined organ offers.[179] As the IOTA Model does for kidney transplantation, understanding and addressing why livers, and possibly other organs, are not chosen for specific patients also has the potential to lead to improved outcomes and longer lives.

i. Organ Transplant Affinity Group

On September 15, 2023, CMS published a blog post titled ''Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance.'' [180] This blog discussed the formation of OTAG, a Federal collaborative with staff from CMS and HRSA working together to strengthen accountability, equity, and performance to improve access to organ donation, procurement, and transplantation for patients, donors, families and caregivers, and providers. The IOTA Model is a part of this coordinated effort from the OTAG and relies on input from across CMS and HRSA.

C. Provisions of the Regulation

1. Implementing the IOTA Model

In this section III.C of the final rule, we discuss our policies for the IOTA Model, including model-specific definitions and the general framework for implementation of the IOTA Model. The upside risk payments owed to the IOTA participants and the downside risk payments owed to CMS are designed to increase access to kidney transplants for patients with ESRD on the IOTA participant's waitlist. As described in section I of this final rule, access to kidney transplants varies widely by region and across transplant hospitals, and disparities by demographic characteristics are pervasive, raising the need to strengthen and improve performance by kidney transplant hospitals. We theorize that the IOTA Model financial incentives will promote improvement activities across selected transplant hospitals that address access barriers, including SDOH, thereby increasing the number of transplants, quality of care, and the provision of cost-effective treatment. Selected transplant hospitals may be motivated to revisit processes and policies around deceased and living donor organ acceptance to identify opportunities for improvement. The IOTA Model payments incentivize selected transplant hospitals to engage in care delivery transformation to better coordinate and manage patient care and needs, invest in infrastructure, improve the patient, family, and caregiver experience, and engage a care delivery team that is tasked with holistic patient care.

a. Model Performance Period

In section III.C.1.a of the proposed rule, we proposed a 6-year ''model performance period.'' We proposed to define the model performance period as the 72-month period from the model start date, comprised of 6 individual PYs. The IOTA participants' performance would be measured and assessed during the model performance period for purposes of determining their performance-based payments. We proposed to define the ''performance year'' (PY) as a 12-month calendar year during the model performance period. We proposed to define the start of the model performance period as the ''model start date,'' and we proposed a model start date of January 1, 2025, meaning that PY 1 would be January 1, 2025, to December 31, 2025, and the model performance period would end on December 31, 2030. We proposed a 6-year model performance period to allow sufficient time for selected transplant hospitals to invest in care delivery transformation and realize returns on investments.

We alternatively considered a 3- or 5-year model performance period; however, we believe that a 3-year model performance period would be too short to allow adequate time for selected transplant hospitals to invest in care delivery transformations. Additionally, our analyses detailed in section V of this final rule project that considerable savings to Medicare will be achieved after the fifth PY, which is another reason why we proposed a 6-year model performance period. We also considered a 10-year model performance period similar to some more recent Innovation Center models; however, given that this is a mandatory model, we felt it was important to limit the duration of the initial test to a shorter period.

We alternatively considered proposing to begin the IOTA Model on April 1, 2025, or July 1, 2025, to allow selected transplant hospitals more time to prepare to implement the model and to better align the model performance period with that of our data sources, as detailed in section III.C.5.a of this final rule. However, we proposed a January 1, 2025, start date because we believed that there would be sufficient time for IOTA participants to prepare for the model. A proposed start date of January 1, 2025, also aligned with other CMS calendar year rules. We separately proposed that in the event the model start date is delayed from the proposed start date, the model performance period for the entire model would be 6

''Good'' Organs Are Turned Down. *American Journal of Transplantation,* 7, 1404–1411. *https://doi.org/10.1111/j.1600-6143.2007.01784.x.*

[174] OPTN/SRTR 2020 Annual Data Report. 2020. Liver. Figures LI 49, 50.

[175] OPTN/SRTR 2021 Annual Data Report. Pancreas. Figures PA 39, 43.

[176] OPTN/SRTR 2021 Annual Data Report. Heart. Figure HR 52.

[177] Merion, R.M., Schaubel, D.E., Dykstra, D.M., Freeman, R.B., Port, F.K., & Wolfe, R.A. (2005). The Survival Benefit of Liver Transplantation. *American Journal of Transplantation, 5*(2), 307–313. *https://doi.org/10.1111/j.1600-6143.2004.00703.x.*

[178] Ross, K., Patzer, R.E., Goldberg, D.S., & Lynch, R.J. (2017). Sociodemographic Determinants of Waitlist and Posttransplant Survival Among End-Stage Liver Disease Patients. *American Journal of Transplantation, 17*(11), 2879–2889. *https://doi.org/10.1111/ajt.14421.*

[179] Lai, J.C., Feng, S., & Roberts, J.P. (2012). An Examination of Liver Offers to Candidates on the Liver Transplant Wait-List. *Gastroenterology, 143*(5), 1261–1265. *https://doi.org/10.1053/j.gastro.2012.07.105.*

[180] Moody-Williams, J., Nair, S. Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance. CMS Blog, September 15, 2023. *https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

PYs, with each PY being a 12-month period that begins on the model start date. For example, if the IOTA Model were to begin on April 1, 2025, ''performance year'' would be defined as a 12-month period beginning on the model start date, meaning April 1, 2025, to March 31, 2026. As a result, the model performance period would also shift to include a 72-month period from the model start date. In this example, the model performance period would be April 1, 2025, to March 31, 2031.

We sought comment on the proposed model performance period of 6 years and the proposed model start date. We also sought comment on the alternative model performance periods that we considered of 3, 5, and 10 years. Finally, we sought comment on the alternative start dates of April 1, 2025, and July 1, 2025, and the subsequent adjustments to the model performance period if the model start date were to change.

Comment: A few commenters supported the proposed model length of six years, indicating that is an appropriate length of time to be able to evaluate a model to determine success.

Response: We thank the commenters for the support and agree a six-year model test should provide sufficient evidence to determine if the IOTA Model is achieving its goals of improving quality of care and reducing Medicare expenditures.

Comment: Several commenters expressed concern around the six-year model performance period. A few commenters felt that a post-transplant evaluation time horizon of six-years contradicts the current OPTN standard of one to three years of post-transplant follow-up. A few commenters also felt that six-years is too long of a model performance period as a shorter model performance period may allow for more immediate assessment and refinement and an adjustment period for unintended consequences. Finally, a commenter felt that the six-year model performance period should be suspended in the event that CMS changes the organ acquisition methodology as initially proposed in the Fiscal Year 2022 Hospital Inpatient Prospective Payment System notice of proposed rulemaking in order to first evaluate the unintended consequences of that proposed change.

Response: We appreciate commenters expressing concern about the six-year model performance period. We believe a six-year model performance period is necessary to allow selected kidney transplant hospitals enough time to invest in care delivery changes necessary for success under the model. CMS research also shows that savings to the Medicare trust fund occur after at least five years of a model performance period. We disagree that a six-year model performance period contradicts current OPTN metrics given that the main focus of the model is to increase the number of transplants year over year, and not to follow post-transplant outcomes after six years. We believe the composite graft survival ratio discussed in section III.C.5.e(1) of this final rule does not contradict the OPTN standard of one to three years of post-transplant follow-up, but rather expands upon existing metrics. Furthermore, models are constantly evaluated and modified even during the model performance period through subsequent rulemaking. A shorter model performance period is not required to make changes responsive to IOTA participant feedback.

We recognize that there may be other efforts occurring simultaneously with the implementation of the IOTA Model, such as the OPTN Modernization efforts and the implementation of the updated OPO Conditions for Coverage. We believe these efforts are synergistic rather than antagonistic because they broadly share the aims of increasing the number of successful transplants and improve quality outcomes for transplant recipients. Therefore, we do not believe that we need to make changes to the six-year model performance period.

Comment: Several commenters felt that the proposed January 1, 2025, model start date did not provide sufficient time for selected transplant hospitals to authorize necessary investments, understand updated organ offer patterns from the updated kidney allocation system, and understand model performance goals. A few commenters also noted that a January 1, 2025, start date would fall outside of the standard hospital institutional budgeting cycle, which would complicate implementation investments. In response, a few commenters supported the alternative model start date discussed in the proposed rule of July 1, 2025, and a few commenters suggested a January 1, 2026, model start date.

Response: We appreciate comments expressing concerns around the timing of this model. We are sensitive to commenters' concerns about the level of preparation needed to implement care redesign activities and develop stakeholder and personnel relationships and processes, especially for hospitals new to value-based care. As such, we are modifying our proposal and finalizing a model start date of July 1, 2025, to allow the selected transplant hospitals more time to prepare for model implementation, and to allow for inclusion of any necessary investments as a result of the IOTA Model in the annual hospital budget cycle. As discussed in section III.C.8 of this final rule, several requirements are voluntary in this first year to allow IOTA participants a grace period to determine how they will implement these requirements and focus on achieving success under the model.

Comment: A few commenters suggested that CMS delay the start of the model until after the request for proposal process for the OPTN is complete, as the possibility of new contractors and multiple vendors could present a risk for errors to attribution which would inhibit beneficiary notification and full implementation of the program.

Response: We thank commenters for their concern regarding the potential overlap between the IOTA Model and the OPTN request for proposal process. HRSA is in the process of conducting their solicitation as part of the OPTN Modernization Process. They released their first requests for proposals in May 2024 and are conducting a series of procurements to support OPTN operations. HRSA has committed to ensuring smooth continued operation of the transplant system and the OPTN, stating that ''while modernization work is complex, the integrity of the organ matching process is paramount and cannot be disrupted.'' [181] At this time, we do not believe that this OPTN Modernization Process would disrupt the beneficiary attribution process of the IOTA Model because attribution status is based on waitlisting, which has not been subject to any major changes during the OPTN modernization process. We will continue to monitor the operation of the model to determine if there are any unforeseen circumstances.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing without modification the proposed definition of model performance period at § 512.402. In light of the public comments, we are also finalizing an alternative model start date of July 1, 2025. As such, we are finalizing our proposed definition for model start date at § 512.402 with slight modification to specify a July 1, 2025, model start date, and finalizing our proposed definition for performance year at § 512.402 with modification to specify a 12-month period beginning on July 1 and ending

[181] *https://www.hrsa.gov/about/news/press-releases/organ-procurement-transplantation-network-modernization-initiative.*

the following June 30 of each year during the model performance period.

b. Other Proposals

We are also finalizing additional policies for the IOTA Model, including the following: (1) the method for selecting transplant hospitals for participation; (2) the schedule and methodologies for the performance-based payments, and waivers of certain Medicare payment requirements solely as necessary to test these payment methodologies under the model; (3) the performance assessment methodology for selected transplant hospitals, including the proposed methodologies for patient attribution, target setting and scoring, and calculation of performance across the achievement domain, efficiency domain, and quality domain; (4) monitoring and evaluation; and (5) overlap with other Innovation Center models and CMS programs.

We proposed that IOTA participants would be subject to the general provisions for Innovation Center models specified in 42 CFR part 512 subpart A and in 42 CFR part 403 subpart K, effective January 1, 2025. The general provisions at subpart A of part 512 are also the subject of revisions in this final rule. As described in section II.B. of this final rule, we proposed to expand the applicability of the general provisions for Innovation Center models to provide a set of standard provisions for Innovation Center models that are applicable more broadly across Innovation Center models. We believed that this approach would promote transparency, efficiency, and clarity in Innovation Center models and avoid the need to restate the provisions in each model's governing documentation. We believed that applying these provisions to the IOTA Model would also promote these purposes.

We sought comment on our proposal to apply the general provisions for Innovation Center models, or the proposed standard provisions for Innovation Center models, to the IOTA Model.

We received no comments on the proposal to make IOTA Participants subject to the general provisions for Innovation Center models, or the standard provisions for Innovation Center models if they were finalized. Therefore, we are finalizing the policy as proposed. Since we are finalizing the proposed revisions to the standard provisions described in section II of this final rule with modification, including that the standard provisions will apply only to the RO Model, the ETC Model, and mandatory Innovation Center models with performance periods that begin on or after January 1, 2025, we are also finalizing our proposal to make the standard provisions for Innovation Center models applicable to the IOTA Model.

2. Definitions

We proposed at § 512.402 to define certain terms for the IOTA Model. We describe these proposed definitions in context throughout section III of this final rule. We proposed to codify the definitions and policies of the IOTA Model at 42 CFR part 512 subpart D (proposed §§ 512.400 through 512.470). In addition, we proposed that the definitions contained in the general provision related to Innovation Center models at subpart A of part 512, and the revisions to those provisions proposed in the notice of proposed rulemaking, would also apply to the IOTA Model. We sought comment on these proposed definitions for the IOTA Model.

We received no comments on these proposals and are therefore finalizing the proposed definitions without modification at § 512.402.

3. IOTA Participants

a. Proposed Participants

We proposed to define ''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, as well as the proposed revisions to that definition, would include an IOTA participant.

We proposed to define ''transplant hospital'' as a hospital that furnishes organ transplants as defined in 42 CFR 121.2. We proposed this definition to align with the definition used by Medicare. We proposed to define ''kidney transplant hospital'' as a transplant hospital with a Medicare approved kidney transplant program. A transplant program, as defined at 42 CFR 482.70, is ''an organ-specific transplant program within a transplant hospital.'' Kidney transplants are the most common form of transplants, but not all transplant hospitals have a kidney transplant program. As the focus of the IOTA Model is kidney transplants, we proposed this definition of kidney transplant hospital to refer specifically to transplant hospitals that perform kidney transplants. We proposed to define ''kidney transplant'' as the procedure in which a kidney is surgically transplanted from a living or deceased donor to a transplant recipient, either alone or in conjunction with any other organ(s). As described in section III.B.3.c of this final rule, the vast majority of kidney transplants are performed alone. However, we believed that it is necessary to include in the definition of kidney transplant those kidney transplants that occur in conjunction with other organ transplants to avoid creating a disincentive for multi-organ transplants within the IOTA Model.

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. 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 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, including SDOH, 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. As described in section III.B.2.a of this final rule, kidney transplant access and acceptance rates vary nationally across kidney transplant hospitals by geography and other demographic and socioeconomic factors. The Innovation Center has implemented models targeting dialysis facilities and nephrology providers, including in the CEC, ETC, and KCC Models. CMS has also implemented changes to the OPO CfCs to strengthen performance accountability for OPOs. However, kidney transplant hospitals have not been the principal focus of any Innovation Center models to date. Expanding accountability to kidney transplant hospitals—key players in the transplantation ecosystem for ESRD patients—aligns with the larger efforts across CMS and HRSA to improve performance and address disparities in kidney transplantation.

We alternatively considered having the IOTA participants be accountable care organizations (ACOs), such as a kidney transplant ACOs, instead of individual kidney transplant hospitals. In this alternative conception, a kidney transplant ACO would form as a

separate legal entity, potentially including kidney transplant hospitals, OPOs, transplant surgeons, and other provider types. The kidney transplant ACO would assume accountability for the number of kidney transplants, equity in the distribution of transplants, and the quality of transplant services from the point of a patient being waitlisted to after a transplant recipient's condition stabilizes following transplantation. This alternative would potentially carry some advantages in the potential for improved coordination among individual providers and suppliers in the kidney transplant ACO, but we believe that it would be administratively burdensome, as it would require the formation of an ACO governing board distinct from the governing boards of individual providers. In addition, such an ACO arrangement would potentially be subject to additional Federal, State, and tribal laws with respect to grievance, licensure, solvency, and other regulations, as well as considerable overlap with other ACO-based Innovation Center models. We therefore proposed to define ''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.

We further alternatively considered requiring OPO participation in the IOTA Model as the entity charged with identifying eligible donors and securing organs from deceased donors (89 FR 43540). However, in 2020, CMS issued a final rule that updated OPO CfC requirements to receive Medicare and Medicaid payment (85 FR 77898). This final rule focuses on holding OPOs in the transplant ecosystem accountable for improving performance, and the Innovation Center does not plan further interventions regarding OPOs at this time. Given the interactions between OPOs and transplant hospitals throughout the donation process, transplant hospitals may wish to collaborate or partner with OPOs on strategies to increase donation and other quality improvement activities.

We sought public comment on the proposal that the IOTA participants would be kidney transplant hospitals.

The following is a summary of the comments received on our proposal that the IOTA participants would be kidney transplant hospitals and our responses:

Comment: Several commenters expressed support for the proposed definition of IOTA participants.

Response: We thank the commenters for their support.

Comment: A commenter sought clarification on the definition of ''kidney transplant'' and whether safety-net kidney transplants would still be counted as kidney transplantations in the year following a liver, heart, and/or lung transplant(s).

Response: We thank the commenter for their input. As described and finalized in this section, kidney transplant means the procedure in which a kidney is surgically transplanted from a living or deceased donor to a transplant recipient, either alone or in conjunction with any other organ(s).

A September 2023 OPTN proposal established criteria for prioritizing patients who previously received either a heart or lung transplant, and now need a kidney transplant. This prioritization is referred to as a ''safety net'' for these patients.[182] As such, we clarify that safety-net kidney transplants will be counted as kidney transplantations in the year following a liver, heart, or lung transplant(s).

After careful consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing the definitions of IOTA participant and kidney transplant at § 512.402 as proposed without modification. We did not receive any comments on our proposed definitions of transplant hospital and kidney transplant hospital and are therefore finalizing these definitions as proposed without modification at § 512.402. Additionally, we note that we intend to publicly post kidney transplant hospitals selected to participate in the model and information regarding the participant selection process, as described and finalized in section III.C.3.d(1) of this final rule, and how it resulted in the list of DSAs.

b. Proposed Mandatory Participation

We proposed that all kidney transplant hospitals that meet the eligibility requirements contained in section III.C.3.c of the proposed rule, and that are selected through the participation selection process contained in section III.C.3.d of the proposed rule, would be required to participate in the IOTA Model. We believe that 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 in accordance with section 1115A(b)(4) of the Act. 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 proposed policies on Medicare savings, kidney transplant volume, kidney transplant acceptance rates, health equity, and quality of care.

In the proposed rule we stated that, nationally, kidney transplant hospitals serve diverse patient populations, operate in varied organizational and market contexts, and differ in size, staffing, and capability (89 FR 43541). There is also wide variation across kidney transplant hospitals on performance on kidney transplant access and organ offer acceptance rate ratios by geography and other demographic and socioeconomic factors. We believed that selection bias would be a challenge in a voluntary model because the IOTA Model would include financial accountability on access to kidney transplants and quality of care, as well as downside risk for kidney transplant hospitals that score poorly on the performance domains. Voluntary participation could result in certain kidney transplant hospitals choosing not to participate in the model and ultimately could inhibit the model from testing a representative sampling of kidney transplant hospitals. We explained in the proposed rule that a mandatory model would address potential selection bias concerns that would exist for a voluntary model by ensuring that our model reaches ESRD patients residing in underserved communities and including other safeguards against selection bias.

As described in section III.C.3.b of the proposed rule, we alternatively considered making participation in the IOTA Model voluntary. However, we were concerned that a voluntary model would not be evaluable, would result in insufficient numbers of kidney transplant hospital participants, and would not be representative of kidney transplant hospitals and ESRD patients nationally. These concerns reflected our expectation that the proposed payment approach would disproportionately attract kidney transplant hospitals already performing well in kidney transplant volume, organ offer

[182] James. (2024, January 31). *FAQ: New Multi-organ polices in effect.* UNOS. *https://unos.org/news/faq-safety-net-policies-for-multi-organ-transplantation/* American Organ Transplant Association. (n.d.). Establish eligibility criteria and safety net for heart-kidney and lung-kidney allocation. U.S. Department of Health and Human Services. Retrieved November 9, 2024, from *https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-eligibility-criteria-and-safety-net-for-heart-kidney-and-lung-kidney-allocation/#:~:text=At%20a%20glance&text=The%20eligibility%20is%20based%20on,safety%20net%E2%80%9D%20for%20these%20patients.*

acceptance rate ratios, and quality of care pre- and post-transplantation, as they would expect to receive upside risk payments. Kidney transplant hospitals already positioned to score high in the IOTA Model's achievement, efficiency, and quality domains may be more likely to join the model than other kidney transplant hospitals, as they would expect to receive upside risk payments. This may be especially true for kidney transplant hospitals that would stand to benefit the most from a model that rewards an increase in the number of kidney transplants. We believed that selection bias in a voluntary model would also limit our ability to assess systematic differences in the IOTA Model's effects on kidney transplant disparities and may further widen disparity gaps for underserved communities that stand to lose if the model does not reach them. We therefore proposed that the IOTA Model would be mandatory for all eligible kidney transplant hospitals selected for participation in the model, as we believed this would minimize the risk of potential distortions in the model's effects on outcomes resulting from hospital self-selection.

We sought public comment on our proposal to make participation in the IOTA Model mandatory.

The following is a summary of the comments received on our proposal to make participation in the IOTA Model mandatory and our responses:

Comment: Several commenters expressed support for requiring mandatory participation in the IOTA Model. Some commenters expressed that mandatory participation would help increase access to kidney transplants and improve kidney transplant outcomes.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern with making participation in the IOTA Model mandatory. Commenters shared that mandatory participation could negatively impact patients. A commenter stated that CMS wrongly presumes that all IOTA participants have the same opportunity for success in the model, and that careful analysis is required to determine whether IOTA Model participation would improve quality of care without sacrificing financial viability. Moreover, a commenter suggested that the nature of mandatory models diverts critical resources that could be used for patient care and instead would redirect resources to administrative tasks, causing administrative burden, in order for transplant hospitals to comply with a mandatory model's unproven and experimental requirements. This commenter also noted that mandatory participation in the IOTA Model could be particularly burdensome for hospitals operating with small financial margins.

Response: We thank the commenters for their feedback. As described in section III.C.3.b of the proposed rule, we believe that 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 proposed policies on Medicare savings, kidney transplant volume, kidney transplant acceptance rates, health equity, and quality of care. Transplant hospitals may have to make upfront investments to accommodate the IOTA Model's requirements, but we believe that the low volume threshold of 11 adult kidney transplants performed during each of the baseline years, as described and finalized in section III.C.3.c of this final rule, will substantially mitigate the demands placed on smaller transplant hospitals. Additionally, we do not believe the IOTA Model will divert critical or financial resources, nor do we believe the IOTA Model will negatively impact patient care. Rather, we believe the incentives of the IOTA Model will complement other efforts in relation to the transplant ecosystem to enhance health and safety outcomes, increase transparency, increase the number of transplants, and reduce disparities. For these reasons, we are finalizing our proposal without modification.

Comment: Multiple commenters suggested that introducing a mandatory payment model on top of existing modernization initiatives would add unnecessary disruption, risk, and uncertainty to the transplant system. A commenter highlighted a specific initiative, the OPTN Modernization Initiative launched in March 2023, which focuses on five key areas: technology, data transparency and analytics, governance, operations, and quality improvement and innovation. A commenter also noted that, alternatively, a voluntary model would minimize disruption for transplant programs whose regulatory environment is already uncertain.

Response: We thank the commenters for their feedback. We recognize the challenges kidney transplant hospitals may face as a result of participation in the IOTA Model. However, as described in section III.C.3.b of the proposed rule, we believe that a mandatory model is necessary to ensure 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. For these reasons, we are finalizing our proposal without modification.

Comment: A commenter suggested that the IOTA Model has the same goals as the ETC Model, and the commenter stated that the ETC Model has not indicated any significant increase in kidney transplants or significant increase in patient placement on kidney transplant waitlists or reduced Medicare spending. The commenter stated that as a result, CMS should not implement a similar mandatory model.

Response: We thank the commenter for their feedback. As described in section III.A of the proposed rule, this model falls within a larger framework of activities initiated by the Federal Government during the past several years and forthcoming in the near future to enhance the donation, procurement, and transplantation of solid organs. Relatedly, as described in section III.B.3.b in this final rule, the IOTA Model proposes to complement the ETC Model and expand kidney model participation to kidney transplant hospitals, which are a key player in the transplant ecosystem, to test whether two-sided risk payments based on performance increase access to kidney transplants for ESRD patients placed on the waitlists of participating transplant hospitals. We disagree with the suggestion that the ETC Model and the IOTA Model have the same goals. No prior CMS models have focused squarely on transplant hospitals in the way the IOTA Model does. For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters raised concerns about bias and disparities as a result of mandatory model participation, suggesting it could bias the model in favor of underperforming transplant hospitals or increase disparities for underserved populations, such as dual-eligible and low-income subsidy beneficiaries, or rural transplant hospitals already impacted by population variability that constricts the ease of access to transplant care.

Response: We thank the commenters for their feedback and concern. As described in section III.C.3.b of the

proposed rule, we believe that 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 proposed policies on Medicare savings, kidney transplant volume, kidney transplant acceptance rates, health equity, and quality of care. We also believe the burden on smaller kidney transplant hospitals will be minimized as a result of the low volume threshold of 11 adult kidney transplants performed during each of the baseline years, as described and finalized in section III.C.3.c of this final rule.

Additionally, we do 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. Rather, we believe the IOTA Model will incentivize IOTA participants to perform a greater number of kidney transplants, including those for underserved populations. We believe that the IOTA Model will encourage IOTA participants to address access barriers low-income patients often face, such as transportation, remaining active on the kidney transplant waiting list, and making their way through the living donation process. Relatedly, while rural transplant hospitals face additional unique challenges, such as geographic difficulties in accessing care, we do not believe underserved populations will be negatively impacted by the IOTA Model's mandatory nature. Rather, as described in section III.B.3.e, differences among transplant hospitals in living donor kidney donation are correlated with geographic region and the number of deceased donor kidney transplantations performed. This underscores the need for initiatives and processes among transplant hospitals, such as the IOTA Model, to encourage living donations to reduce geographic disparities. For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters suggested that a mandatory model has financial risks to model participants due to high upfront costs related to employees and IT support, and that it places model participants at significant financial risk regardless of their readiness for participation. Commenters stated that a mandatory model effectively cuts compensation for kidney transplant hospitals with insufficient resources to adequately participate, thereby exacerbating resource disparities and impacting the viability of some transplant programs. Commenters also stated that kidney transplant hospitals selected to participate in the model may opt out of performing kidney transplants rather than assume the costs of mandatory participation.

Response: We thank the commenters for their feedback and concern. As described in section III.C.3.b of the proposed rule, we believe that a mandatory framework is essential to ensure that a sufficient number of kidney transplant hospitals participate in the IOTA Model such that CMS will be able to conduct an adequate evaluation of the model's effects on cost and quality of care. Kidney transplant hospitals selected to participate in the model may have to make upfront investments to accommodate the IOTA Model's requirements, but we believe that the low volume threshold of 11 adult kidney transplants performed during each of the baseline years, as described and finalized in section III.C.3.c of this final rule, will substantially mitigate the demands placed on smaller kidney transplant hospitals. With several months of lead time until the IOTA Model's start date, we believe eligible kidney transplant hospitals selected to participate in the IOTA Model will be sufficiently equipped for participation and success in the model. We do not believe mandatory participation will cut compensation for smaller kidney transplant hospitals selected to participate in the IOTA Model. Rather, mandatory participation in the IOTA Model offers a strong financial incentive for those transplant hospitals chosen to participate. Finally, we believe the two-sided performance-based payment structure, as described and finalized in section III.C.6.a of this final rule, which rewards IOTA participants for high performance in the achievement, efficiency, and quality domains—and imposes financial accountability on IOTA participants that perform poorly on those domains—will encourage maximum engagement from IOTA participants. For these reasons, we are finalizing our proposal without modification.

Comment: Multiple commenters showcased the differing opinions regarding how the mandatory nature of the IOTA Model may impact kidney transplant hospitals based on size. Some commenters suggested that mandatory participation could benefit lower-volume or underperforming kidney transplant hospitals that have room to grow, while larger-volume kidney transplant hospitals with limited capacity to grow would incur financial and administrative burdens to reach their transplant targets. Other commenters suggested the IOTA Model could negatively impact small kidney transplant hospitals financially. or increase competition for available organs with higher-volume kidney transplant hospitals.

Response: We thank the commenters for their support and feedback. IOTA participant performance on the achievement domain in the IOTA Model is measured based on the number of transplants performed by the IOTA participant in the baseline years and the national growth rate as described and finalized in section III.C.5.c(1) of this final rule. As a result of this metric, we believe kidney transplant hospitals—including larger-volume programs in the IOTA Model—are on equal footing to improve their transplant rates in each consecutive PY. IOTA participants may have to make upfront investments to accommodate the IOTA Model's requirements, but we believe that the required low volume threshold of 11 adult kidney transplants performed for each kidney transplant hospital in each of the baseline years, as described and finalized in section III.C.3.c of this final rule, will substantially mitigate the demands placed on smaller kidney transplant hospitals. Additionally, we have found that many of these kidney transplant hospitals consistently perform between 11 and 50 kidney transplants annually. We direct readers to section III.C.3.c of this final rule for a full discussion on why we believe provisions within the IOTA Model will limit negative impacts to small kidney transplant hospitals.

We recognize that IOTA participants face varying challenges based on their kidney transplant volumes. However, we believe all IOTA participants, including high-volume kidney transplant hospitals, have opportunities to increase the number of kidney transplants performed. For example, high-volume kidney transplant hospitals could focus on improving deceased donor organ utilization or supporting more living donors. Regardless of each IOTA participant's approach or any potential competition, we intend to monitor the model for any unintended consequences. For these reasons, we are finalizing our proposal without modification.

Comment: A commenter suggested that mandatory participation in the IOTA Model may be undermined by the absence of any meaningful adverse consequences when an IOTA participant is terminated from the model.

Response: We thank the commenter for their feedback. As described and finalized in section III.C.16.a of this final rule, we may take a variety of one or more remedial actions. We believe the remedial actions we are finalizing at § 512.464(b) can meaningfully discourage noncompliance with the IOTA Model requirements. For these reasons, we are finalizing our proposal without modification.

Comment: A commenter claimed that CMS does not have the authority to institute IOTA as a mandatory model, while other commenters shared general concerns about requiring mandatory participation in the model.

Response: We thank the commenters for their feedback and concerns. CMS' testing of innovative payment and service delivery models, including the IOTA Model, complies with section 1115A of the Act and other governing laws and regulations, including the U.S. Constitution. Section 1115A of the 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. Section 1115A of the Act authorizes the Secretary to test innovative payment and service delivery models expected to reduce Medicare costs while preserving or enhancing quality of care. 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. Section 1115A(b)(2)(B) of the Act describes a number of payment and service delivery models that the Secretary may test, but the Secretary is not limited to testing just those models. Rather, as specified in section 1115A(b)(2) of the Act, models to be tested under section 1115A of the Act must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The IOTA Model addresses a defined population (kidney transplant waitlist patients) for which there are potentially avoidable expenditures arising from an inadequate number of kidney transplants performed each year.

We 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.

Moreover, the Secretary has the authority to establish regulations to carry out the administration of the Medicare program. Specifically, the Secretary has authority under sections 1102 and 1871 of the Act to implement regulations as necessary to administer the Medicare program, including testing this Medicare payment and service delivery model. We note that IOTA is not a permanent feature of the Medicare program. Rather, IOTA will test innovative methods for delivering and paying for services covered under the Medicare program, which the Secretary has clear legal authority to regulate. The proposed rule went into detail about the provisions of the proposed IOTA Model, enabling the public to understand how IOTA was designed and could apply to affected kidney transplant hospitals. and sought comment on the proposed model design and policies. As permitted by section 1115A of the Act, we are testing IOTA within specified geographic areas. If the IOTA Model test meets the statutory requirements for expansion, and the Secretary determines that expansion is appropriate, we would undertake rulemaking to implement the expansion of the scope or duration of the IOTA Model to additional geographic areas or for additional time periods, as required by section 1115A(c) of the Act.

For these reasons, we are finalizing our proposal without modification.

Comment: Multiple commenters suggested the IOTA Model should begin with a voluntary trial period or be a purely voluntary model to minimize negative impacts on patients. They cautioned that an unintended consequence of this mandatory model could be a decrease the availability of marginal organs for transplantation. Several other commenters recommended the IOTA Model allow self-selection to encourage participation from motivated kidney transplant hospitals. These commenters suggested this would incentivize voluntary participation and enable kidney transplant hospitals to assess if the model is appropriate for their patients.

Response: We thank the commenters for their feedback. As described in section III.C.3.b of the proposed rule, we believe that 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 as required by section 1115A(b)(4) of the Social Security Act. We believe a voluntary trial period would inhibit this evaluation.

More specifically, we are concerned that a voluntary model would not be evaluable, result in insufficient numbers of IOTA participants, and not be representative of kidney transplant hospitals and ESRD patients nationally. These concerns reflect our expectation that the model's proposed payment approach, as described and finalized in section III.C.6 of this final rule, would disproportionately attract kidney transplant hospitals already performing well in kidney transplant volume, organ offer acceptance rate ratios, and quality of care pre- and post-transplantation. Kidney transplant hospitals already positioned to score high in the IOTA Model's achievement, efficiency, and quality domains may be more likely to join the model than other kidney transplant hospitals, as they would expect to receive upside risk payments. In the context of the IOTA Model, we believe that a voluntary model could result in selection bias and limit our ability to assess systematic differences in the IOTA Model's effects on kidney transplant disparities.

As a mandatory model, we also believe the IOTA Model will have positive impacts on patients and an increase in the availability of kidneys. Finally, we believe the transplant hospitals selected for mandatory participation would be motivated to increase the number of kidney transplants performed due to the financial incentives of the model. For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters expressed concern with making participation in the IOTA Model mandatory, urging CMS to consider geographic factors or the impact of the model on smaller kidney transplant hospitals. For example, a commenter argued that the IOTA Model's mandatory participation component must consider geographic location. The commenter explained that if the model aims to address disparities in transplant access for patients of different races, ethnicities, socioeconomic statuses, or from rural areas, then these factors need to be accounted for. The commenter stated that they see these factors directly impacting their pool of potential living donors, who often suffer from the same medical and economic conditions as their recipients and thus get ruled out.

A commenter from a smaller, rural kidney transplant hospital expressed concerns about mandatory participation. They argued that population density varies greatly in their rural state, with an uneven distribution. The commenter noted this population variation impacts both access to transplant care and the available donor pool and would require additional staffing and resources to manage the model effectively.

Another 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.

Lastly, a commenter recognized that the IOTA participants would be kidney transplant hospitals. The commenter reiterated concerns about the challenges that mandatory payment models may pose for physician practices. The commenter explained that successful participation in alternative payment models often requires new investments in infrastructure and technical capabilities, such as sophisticated data management, dedicated performance assessment resources, and updates to electronic medical records. They argued that meeting these demands would be difficult, if not impossible, for many kidney transplant hospitals, especially smaller ones. This could set these kidney transplant hospitals up for failure. The commenter recommended that CMS apply exemptions or special accommodations, like upside-only risk, for small kidney transplant hospitals that lack experience with value-based payment arrangements, if CMS requires future participation in new models.

Response: We took into consideration geographic factors when proposing to stratify the DSAs into groups based on each DSA's Census Division and the total number of adult kidney transplants performed annually across all eligible kidney transplant hospitals in each DSA during the baseline years for the first PY, as described and finalized in section III.C.3.d(1). As discussed in the proposed rule, we believe selecting eligible kidney transplant hospitals from these groups of DSAs will ensure that the IOTA participants represent eligible kidney transplant hospitals nationwide, both geographically and in terms of annual adult kidney transplant volume (89 FR 43542). Additionally, as described and finalized in section III.C.3.d(1) of this final rule, CMS will then select approximately half of all DSAs nationwide using a stratified sampling methodology, and all eligible kidney transplant hospitals in the selected DSAs will be required to participate in the IOTA Model.

Additionally, we note that we intend to publicly post information regarding the selection process and how it resulted in the list of DSAs and kidney transplant hospitals selected to participate in the model.

Finally, as described and finalized in section III.C.3.c of this final rule, we will use a low volume threshold of 11 adult kidney transplants performed during each of the baseline years. This low volume threshold aligns with the minimum requirements for publishing CMS data, ensuring the confidentiality of Medicare and Medicaid beneficiaries by preventing the disclosure of information that could identify individual beneficiaries. As described at 89 FR 43541 in the proposed rule, we alternatively considered using a higher threshold, such as 30 adult kidney transplants or 50 adult kidney transplants during each of the three baseline years. However, we found that many kidney transplant hospitals consistently perform between 11 and 50 kidney transplants annually. For these reasons, we are finalizing our proposal without modification.

After careful consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposal to make the IOTA Model mandatory at § 512.412(c) without modification.

c. Participant Eligibility

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 as discussed in section III.C.5 of this final rule; 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 that eligible kidney transplant hospitals would be those that: (1) performed 11 or more kidney transplants for patients aged 18 years or older annually, regardless of payer type, in each of the baseline years (the ''low volume threshold''); 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 proposed to define ''baseline year'' as a 12-month period within a 3-year historical baseline period that begins 48 months (or 4 years) before the start of each model PY and ends 12 months (or 1 year) before the start of each model PY. For example, if the IOTA Model were to start on January 1, 2025, the 3-year historical baseline period would begin January 1, 2021, and end on December 31, 2023.[183] We proposed to define ''non-pediatric facility'' as a kidney transplant hospital that furnishes over 50 percent of their kidney transplants annually to patients 18 years of age or older. CMS would select approximately half of all DSAs nationwide using a stratified sampling methodology, and all eligible kidney transplant hospitals in the selected DSAs would be required to participate in the IOTA Model.

As described in the proposed rule at 89 FR 43541, the proposed low volume threshold of 11 or more kidney transplants for ESRD patients aged 18 years or older during each of the three baseline years (as described in section I.B.2.b of the proposed rule) would exclude low volume kidney transplant hospitals from the IOTA Model. We believed that these kidney transplant hospitals should be excluded from the model because they may not have the capacity to comply with the model's policies, and because the inclusion of this group of kidney transplant hospitals in the model would be unlikely to significantly alter the overall rates of kidney transplantation. We stated that we were also proposing a low volume threshold of 11 adult kidney transplants because it is consistent with the minimum thresholds for the display of CMS data to protect the confidentiality of Medicare and Medicaid beneficiaries by avoiding the release of information that can be used to identify individual beneficiaries. We alternatively considered using a higher threshold, such as 30 adult kidney transplants or 50 adult kidney transplants during each of the three baseline years. However, we found that many kidney transplant hospitals consistently perform between 11 and 50 transplants per year. We further believe that using a higher threshold would decrease the number, size and location of kidney transplant hospitals eligible to be selected for participation in the IOTA Model, thereby limiting the generalizability of the model test. We also recognize that the number of kidney transplants

[183] This example, which appeared in the notice of proposed rulemaking, has been clarified to specify that the baseline years for each PY would be each 12-month period beginning January 1, 2021, and ending December 31, 2023.

performed by a kidney transplant hospital may fluctuate from year to year, and looking back three years would help determine if a kidney transplant hospital has the capacity to consistently perform 11 or more transplants per year. We sought feedback on this approach for determining which kidney transplant hospitals would be eligible for selection under the model.

We considered including pediatric kidney transplant hospitals as eligible participants in the IOTA Model. However, pediatric kidney transplantation has significantly different characteristics, considerations, and processes from adult kidney transplantation. The number of pediatric kidney transplants performed each year is also exceedingly small, which would present difficulties in reliably determining the effects to the model in the pediatric population. Additionally, a much larger proportion of pediatric kidney transplants are living donor transplants than in the adult population. As such, we do not believe the proposed IOTA Model would function in the same way for both kidney transplant hospitals serving primarily adults and those serving primarily children, and we believe it is necessary to include only non-pediatric kidney transplant hospitals in the IOTA Model.

We sought comment on our proposed participant eligibility criteria for kidney transplant hospitals, including the requirement that a kidney transplant hospital perform 11 or more kidney transplants annually on patients aged 18 years or older during the baseline years. We also sought comment on the proposal to include only kidney transplant hospitals that meet the proposed definition for a non-pediatric facility during the baseline years.

The following is a summary of the comments received on our proposed participant eligibility criteria for kidney transplant hospitals, including the requirement that a kidney transplant hospital perform 11 or more kidney transplants annually on patients aged 18 years or older during each of the baseline years, and the proposal to include only kidney transplant hospitals that meet the proposed definition for a non-pediatric facility during the baseline years, and our responses:

Comment: Several commenters expressed support for the IOTA participant kidney transplant hospital eligibility criteria, as proposed, particularly noting the proposed eligibility criterion by which a kidney transplant hospital must furnish over 50 percent of their kidney transplants annually to patients 18 years of age or older.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern with the proposed low-volume kidney transplant threshold for IOTA participants. 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 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.

Response: We thank the commenters for their feedback. To protect the confidentiality of Medicare and Medicaid beneficiaries, we proposed a low volume threshold of 11 adult kidney transplants. We believe 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 43541). We recognize that this could exclude smaller kidney transplant programs, which may not already meet COE [184] program criteria and have limited contact with payers. However, as described in the proposed rule, we proposed a low volume threshold of 11 adult kidney transplants to exclude low-volume kidney transplant hospitals that may lack the capacity to comply with the model's policies, as their inclusion would be unlikely to significantly impact overall kidney transplant rates (89 FR 43541). We considered, but did not propose, using a higher threshold, such as 30 adult kidney transplants or 50 adult kidney transplants during each of the three baseline years (89 FR 43541). However, we did not propose this, as we found that many kidney transplant hospitals consistently perform between 11 and 50 transplants annually. We maintain our belief that a higher threshold would reduce the number, size, and geographic diversity of kidney transplant hospitals eligible for the IOTA Model, limiting the model's broader applicability. Additionally, we recognize that kidney transplant volumes can fluctuate year-to-year. Furthermore, we believe looking at a 3-year historical baseline period will help assess if a kidney transplant hospital has the capacity to consistently perform 11 or more kidney transplants annually.

Relatedly, as described in section III.C.3.d(2) of this final rule, after the IOTA Model's start date, we do not anticipate making any additional participant selections, unless 10 percent or more of the selected participants are terminated during the model's performance period. If that occurs, we will address the selection of new IOTA participants through future notice and comment rulemaking, and we may reevaluate the low volume threshold.

Finally, as described in the proposed rule, we considered limiting IOTA waitlist and IOTA transplant patients to Medicare beneficiaries only, as Medicare covers over 50 percent of kidney transplants (89 FR 43544). However, we ultimately did not propose this limitation. We believe restricting the IOTA Model assessment to Medicare patients would reduce the sample size, potentially hindering our ability to detect performance changes due to model payments. Therefore, we proposed, and will be finalizing, that the IOTA Model reflect both Medicare beneficiaries and non-Medicare patients for performance assessment, with Medicare beneficiaries being a subset of the patient population attributed to each model participant. We direct readers to section III.C.5 of this final rule for a full discussion on the IOTA Model performance assessment methodology. We believe the same rationale applies for kidney transplant hospital eligibility criteria. For these reasons, we are finalizing our proposal without modification.

Comment: A commenter suggested that IOTA participants that furnish a smaller volume of kidney transplants would have little incentive to engage in the model if participant eligibility is

[184] A transplant center receives Center of Excellence (COE) designation from a private insurer when it meets transplant volume and performance thresholds. Without this designation, a transplant hospital may not be approved by certain private insurance companies to complete a transplant procedure, which limits the transplant center where patients may receive covered care.

based on all kidney transplants, but financial incentives and penalties only apply to Medicare kidney transplants.

Response: We thank the commenter for their feedback. We considered, limiting IOTA waitlist patients and IOTA transplant patients to Medicare beneficiaries only, as Medicare covers more than 50 percent of all kidney transplants from both deceased and living donors (89 FR 43544). However, we believe it's necessary to include all patients, regardless of payer type, in the IOTA participant's performance calculations. This protects against unintended consequences and problematic financial incentives that could arise if the IOTA Model only applied to specific payer types. Additionally, the eligible waitlist and transplant patient population attributed to each IOTA participant is already relatively small, in terms of both transplant candidates and recipients. Limiting the IOTA Model performance assessment, as described in section III.C.5 of this final rule, to only Medicare beneficiaries would further reduce the patient sample size, potentially affecting our ability to detect changes in performance due to model payments. For these reasons, we chose not to propose limiting IOTA waitlist patients and IOTA transplant patients to Medicare beneficiaries only and respectfully disagree with the commenter.

Lastly, as described in section III.C.5 of this final rule, the IOTA Model's performance assessment is inclusive of both Medicare and non-Medicare patients. We believe this will incentivize IOTA participants of all sizes and patient populations to fully engage in the model regardless of payer type. For these reasons, we are finalizing our proposal without modification.

Comment: Multiple commenters recommended that CMS exclude kidney transplant hospitals with high volume, high quality, and high efficiency from the IOTA Model, and provide additional provisions for newer kidney transplant hospitals.

Response: We thank the commenters for their feedback. As described in section I.B.2.b of the proposed rule, we proposed to select the kidney transplant hospitals that will be required to participate in the IOTA Model from the group of eligible kidney transplant hospitals using a stratified random sampling of DSAs to ensure that there is a fair selection process and representative group of participating kidney transplant hospitals. We believe the commenter's recommendation would inhibit a representative sampling necessary to the IOTA Model. For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters suggested CMS should change multiple aspects of the proposed participant eligibility criteria. Recommendations included excluding kidney transplant hospitals that have had a transplant volume growth of 30 percent or more and expanding eligible kidney transplant hospitals to include pediatric kidney transplant hospitals.

Response: We thank the commenters for their feedback and suggestions. In section I.B.2.b of the proposed rule, we proposed to select the kidney transplant hospitals that will be required to participate in the IOTA Model from the group of eligible kidney transplant hospitals using a stratified random sampling of DSAs to ensure that there is a fair selection process and representative group of participating kidney transplant hospitals. We believe the commenter's recommendation would inhibit a representative sampling necessary to test the proposed model. For these reasons, we are finalizing our proposal without modification.

Additionally, regarding the comments that CMS consider including pediatric kidney transplant hospitals in the IOTA Model, we acknowledge the importance kidney transplantation for pediatric patients. As described at 89 FR 43541 in the proposed rule, we considered, including pediatric kidney transplant hospitals in the IOTA Model. However, for the reasons described in section III.C.5.c of this final rule, we ultimately decided not to propose their inclusion as eligible kidney transplant hospitals. pediatric kidney transplant hospitals as eligible participants in the model. As such, we respectfully disagree with commenters who argued that pediatric kidney transplant hospitals should be eligible to participate in the model.

Finally, as described in the proposed rule, we considered offering differential credit for transplants by type (89 FR 43553). With this alternative methodology, IOTA participants would receive bonus points and score higher for transplants that fit into categories that lead to more savings, such as living donor kidney transplants, high kidney donor profile index donors, or pre-emptive transplants, compared to other transplants. However, we chose not to propose a methodology that provides differential credit for transplants based on type, as we believe that counting all transplants equally will give IOTA participants the flexibility to meet their transplant targets. Furthermore, we think this approach of treating all transplants the same helps minimize the potential harm and unintended consequences that could arise from a methodology that offers differential credit based on transplant type. We direct readers to section III.C.5.c(2) of this final rule for a full discussion on alternative methodologies we considered for calculating points in the achievement domain. For these reasons, we are finalizing our proposal without modification.

Comment: A commenter acknowledged that CMS proposed to define a baseline year as a 12-month period within a 3-year historical baseline period, that begins 48 months (or 4 years) before the start of each model PY and ends 12 months (or 1 year) before the start of each model PY. For PY 1 (CY 2025), as proposed, the commenter highlighted that the proposed 3-year historical baseline period consists of CY 2021 through CY 2023. The commenter supported the proposed 3-year historical baseline period for PY 1, noting that 2020–2022 represented a low point in transplant activity due to the Public Health Emergency (''PHE'') declared in response to the COVID–19 pandemic, which reduced the number of kidneys transplanted nationally. Additionally, the commenter believed that starting from this low baseline would help ensure more attainable performance improvement targets for model participants, though they still had significant reservations about the proposed transplant targets.

Response: We thank the commenter for their support.

Comment: Multiple commenters expressed concern on the inclusion of 2021 in the baseline years. Specifically, a commenter suggested that the 3-year historical baseline period should exclude transplant data from 2021, as the COVID–19 public health emergency impacted this performance year.

Response: We thank the commenters for their feedback. As described in section III.C.3.c of this final rule, we proposed to define ''baseline year'' as a 12-month period within a 3-year historical baseline period that begins 48 months (or 4 years) before the start of each model PY and ends 12 months (or 1 year) before the start of each model PY. For example, if the IOTA Model were to start on July 1, 2025, the 3-year historical baseline period would begin July 1, 2021, and end on June 30, 2024. In this example, the baseline years for each PY would be 12-month periods beginning July 1, and ending on June 30.

Relatedly, in response to commenters requesting a later start date for the model, we are finalizing a July 1, 2025, model start date. This will result in the

inclusion of only the latter six months of 2021 into the baseline period for the first PY. Within the context of the COVID–19 pandemic, the non-utilization of deceased donor kidneys in 2020 rose to the highest level up to that time, 21.3 percent. Additionally, the number of newly added adult candidates to the waitlist increased 11.7 percent from 2020 to 2021, recovering from the pandemic related decline in the prior year, and exceeding the 2015–2019 CAGR of 9.2 percent. We do not believe inclusion of July through December of 2021 into the baseline year would inhibit the overarching goal of the IOTA Model. For these reasons, we are finalizing our proposal without modification.

After consideration of the public comments we received, we are finalizing our proposed provisions for participant eligibility criteria for kidney transplant hospitals at § 512.412(a) without modification. We received no comments for the proposed definition of non-pediatric facility and are finalizing the proposed definitions of non-pediatric facility, and baseline years at § 512.402 without modification.

d. Participant Selection

(1) Overview and Process for Participant Selection

In section III.C.c.3.d(1) of the proposed rule, we proposed to select eligible kidney transplant hospitals for participation in the IOTA Model using a stratified sampling of approximately half of all DSAs nationwide. We stated that all kidney transplant hospitals that meet the proposed participant eligibility criteria described in section III.C.3.c of the proposed rule and are located in the selected DSAs would be required to participate in the IOTA Model. As defined in 42 CFR 486.302, a ''Donation Service Area (DSA)'' means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area (MSA) or does not include any part of such an area and that meets the standards of subpart G. A DSA is designated by CMS, is served by one OPO, contains one or more transplant hospitals, and one or more donor hospitals. There were 56 DSAs as of January 1, 2024. A map of the DSAs can be found on the SRTR website.[185] CMS would use the list of DSAs as it appears on January 1, 2024, to select the DSAs, and therefore the eligible kidney transplant hospitals that would be required to participate in the IOTA Model.

We proposed this approach for selecting IOTA participants to obtain a group of eligible kidney transplant hospitals that is representative of kidney transplant hospitals from across the country in terms of geography and kidney transplant volume. We proposed to stratify the DSAs into groups based on each DSA's Census Division and the total number of adult kidney transplants performed annually across all eligible kidney transplant hospitals in each DSA during the baseline years for the first PY. Selecting eligible kidney transplant hospitals from these groups of DSAs would ensure that the IOTA participants are representative of eligible kidney transplant hospitals from across the nation in terms of geography and the volume of adult kidney transplants.

A second aim of our proposal to select eligible kidney transplant hospitals from stratified groups of DSAs is to prevent distortions on the effects of the model's policies and features on outcomes. Our analysis of kidney transplant hospital data shows that selecting only some eligible kidney transplant hospitals within a selected DSA to participate in the IOTA Model may shift the supply of deceased donor organs from non-IOTA participants to IOTA participants within the same DSA. The resulting distortions would make it difficult to attribute changes in outcomes to the model and would limit its evaluability.

Our proposed approach for selecting IOTA participants would involve stratifying DSAs into groups based on the average number of adult kidney transplants performed by all eligible transplant hospitals located in the DSA during the baseline years of PY 1. We proposed using this variable to stratify the DSAs into groups because increasing the total number of adult kidney transplants is the primary metric that we proposed to use to evaluate the IOTA participants' performance in the model.

The proposed approach for IOTA participant selection is as follows:

- *Assign all DSAs to a Census Division.*[186] The Census Bureau subdivides the United States into four Census Regions (Northeast, Midwest, South, and West) which are in turn divided into nine Census Divisions. CMS would assign each DSA to a single Census Division. Due to the New England region being both a DSA and a Census Division, CMS would combine the Middle Atlantic and New England Census Divisions for a total of eight Census Divisions. If CMS were to keep the New England Census Division separate, the New England DSA would be guaranteed participation in the model in subsequent steps. As such, we proposed to combine the Middle Atlantic and New England Census Divisions for the purposes of this selection methodology. Some DSAs may span several Census Divisions, but most DSAs will be assigned to the Census Division where the majority of the DSA's population resides according to the 2020 Census data. Puerto Rico is the only DSA which exists outside of a Census Division. This DSA would be assigned to the South Atlantic Census Division as it is the closest geographically. This step would create eight Census Division groups, one for each Census Division (with the exception of the combined Middle Atlantic and New England Census Divisions, which would be grouped together to create one Census Division group).
- *Determine the kidney transplant hospitals located within each DSA.* CMS would list out the kidney transplant hospitals located within each DSA and assigned Census Division group.
- *Identify the eligible kidney transplant hospitals located within each DSA.* CMS would use the criteria noted in section III.C.3.c of the proposed rule to identify the eligible kidney transplant hospitals within each DSA. This step is expected to yield approximately 180 to 200 eligible kidney transplant hospitals total across the eight Census Division Groups.
- *For each DSA, determine the average number of adult kidney transplants performed annually across all eligible kidney transplant hospitals during the baseline years for PY 1.* CMS would use data from the baseline years for PY 1 to determine the average number of adult kidney transplants performed annually across all of the eligible transplant hospitals located in each DSA. CMS would sum the number of adult kidney transplants performed by all of the eligible kidney transplant hospitals in a DSA during each of the baseline years for PY 1 and divide each DSA's sum by three to determine the average number of adult kidney transplants furnished annually during the baseline years by the eligible kidney transplant hospitals located within each DSA.
- *Within each Census Division group, create two mutually exclusive groups of DSAs using the average number of adult kidney transplants performed annually across the baseline years for PY 1.* CMS

[185] *https://www.srtr.org/reports/opo-specific-reports/interactive-report.*

[186] A complete list of DSAs in the United States as of 2022–2023 can be obtained using the data reporting tool found on the SRTR website (*https://www.srtr.org/reports/opo-specific-reports/interactive-report*).

would separate DSAs assigned to a Census Division group into two mutually exclusive groups of DSAs based on the average number of adult kidney transplants performed annually across the baseline years for PY 1. The two groups within each Census Division group would be: (1) DSAs having higher numbers of adult kidney transplants across the baseline years; and (2) DSAs having lower numbers of adult kidney transplants across the baseline years. Since the average number of adult kidney transplants will be different across each DSA, each Census Division group will have a different cut off to create these two groups. To ensure each DSA has a 50 percent chance of being chosen in step 7, each DSA group within a Census Division group should have the same number of DSAs. However, in the event of an odd number of DSAs within a Census Division group, CMS would proceed to step six.

- *For groups within a Census Division group that contain an odd number of DSAs, CMS would randomly select one DSA from the group. Each of these individual selected DSAs would have a 50 percent probability of being selected for the IOTA Model.* For groups within a Census Division group that contain an odd number of DSAs, CMS would randomly select one DSA from the group and determine that individual DSA's chance of selection for inclusion in the IOTA Model with 50 percent probability. Following this step, each group within a Census Division group would have an even number of DSAs.
- *Randomly select 50 percent of remaining DSAs in each group.* CMS would then take a random sample, without replacement, of 50 percent of the remaining DSAs in each group (the groups being DSAs having higher numbers of adult kidney transplants across the baseline years and DSAs having lower numbers of adult kidney transplants across the baseline years) within each Census Division group. All of the eligible kidney transplant hospitals located within the selected DSAs would be required to participate in the IOTA Model.

We proposed that CMS would notify IOTA participants of their selection to participate in the IOTA Model in a form and manner chosen by CMS, such as public notice and email, at least 3 months prior to the start of the model performance period. As described in section III.C.3.b of this final rule, we proposed that participation in the IOTA Model would be mandatory. As such, if an IOTA eligible transplant hospital is located within one of the DSAs that CMS randomly selects for the IOTA Model, the eligible kidney transplant hospital would not be able to decline participation in this model, nor would it be able to terminate its participation in the model once selected. Model termination policies are further discussed in section III.C.16 of this final rule.

We direct readers to section III.C.3.d(2) of this final rule for a summary of the comments received on our proposed approach for selecting IOTA participants and our responses.

(2) Consideration of Alternatives to Proposed Participant Selection Approach

We considered using other geographic units for stratified random sampling to choose IOTA participants, such as Core Based Statistical Areas (CBSAs), Metropolitan Statistical Areas (MSAs), Hospital Referral Regions (HRRs), or States (89 FR 43543). CBSAs, MSAs, HRRs, and States are commonly known geographic units, and have been used as part of participant selection for other Innovation Center models. We believe selecting participants by DSA significantly mitigates behavior that would artificially inflate the model's effects on kidney transplant volume for the reasons described in the preceding section. OPOs associated with selected DSAs would be expected to benefit from consistency in rules across most or all of their transplant hospitals. The Innovation Center found that selecting participants by DSA improved the ability to detect changes in kidney transplant volume to a level consistent with the anticipated change in kidney transplant volume associated with the model's payment rules. Participants from the same DSA are, for the most part, subject to similar levels of kidney supply, and, with the exception of kidneys from another DSA, the same rules for kidney allocation apply. While OPTN recently updated its organ allocation methodology to allow organs to go outside of the DSA in which an organ was procured, many kidney transplant hospitals still receive a plurality of kidneys from the local OPO in their DSA, ensuring that this is still a meaningful method to group kidney transplant hospitals. Using alternative geographic units would negate these advantages.

We also considered other random sampling techniques, including simple random sampling of transplant hospitals, simple random sampling of DSAs, and cluster sampling of DSAs (89 FR 43543). Simple random sampling of hospitals risks oversampling regions of the country where transplant hospitals are concentrated and under sampling areas with fewer eligible transplant hospitals. Using simple random sampling of DSAs may result in an unrepresentative sample of DSAs with a greater risk of oversampling regions where DSAs cover small geographic areas. We considered cluster random sampling where half of all DSAs would be sampled in a first step and half of eligible kidney transplant hospitals within selected DSAs would be sampled. However, because this approach would retain half of eligible kidney transplant hospitals in selected DSAs, we expect the model's effects on kidney transplant volume would be overstated because kidney supply flowing towards non-participant hospitals prior to the start of the model would be redirected towards IOTA participants. In addition, CMS' analyses of these alternative sampling approaches indicated the model would not be evaluable because these approaches were associated with lower precision in detecting changes in kidney transplant volumes due to the model compared to the increase in transplant volume anticipated from the model's payment rules.

As an alternative we also considered other variables to create DSA groups for stratified sampling of DSAs (89 FR 43543). Specifically, after assigning each DSA to a Census Division, we considered stratifying DSAs using the following DSA level variables:

- Number of eligible transplant hospitals in DSA.
- Annual adult kidney transplants per eligible transplant hospital in DSA.
- Average organ offer acceptance rate ratio across eligible kidney transplant hospitals in DSA.
- Average percent of Medicare kidney transplant recipients dually eligible for Medicare and Medicaid or who are LIS recipients.
- Percent of eligible transplant hospitals in DSA participating in the Kidney Care Choices or ESRD Treatment Choices Models.
- Average percent of kidney transplants from a living donor among eligible kidney transplant hospitals in DSA.

These variables were given consideration in the stratified selection approach because their use would create groups of DSAs whose eligible transplant hospitals are more similar to each other on the listed characteristics instead of only adult kidney transplant volume and Census Division. However, we opted to use the simpler stratified participant selection approach to provide greater transparency in the model's participant selection approach.

We also considered stratified random sampling of individual kidney

transplant hospitals using similar variables as those described in the preceding paragraph (89 FR 43543). Although this approach provided representativeness of sampled transplant hospitals along dimensions important for the model, it would be expected to result in a subset of eligible kidney transplant hospitals in at least a portion of DSAs being designated as participants. As we have described previously, we expect that allowing a portion of DSA kidney transplant hospitals to be model participants would result in an overstatement of the model's effects on kidney transplant volume and other outcomes of interest. As with the sampling approaches considered in the preceding paragraph, CMS' analyses indicated the IOTA Model would not be evaluable if stratified sampling of individual kidney transplant hospitals were used in participant selection for the reasons described previously.

As stated at 89 FR 43544 in the proposed rule, CMS expects that no additional participant selections would be made for the IOTA Model after its start date unless 10 percent or more of selected participants are terminated from the model during the model performance period. We stated that if this were to occur, we would address the selection of new participants in future rulemaking.

We sought comment on our proposed approach for selecting IOTA participants and on the alternative approaches considered, including perceived advantages and disadvantages of our proposed participant selection approach relative to alternatives.

The following is a summary of the comments received on our proposed approach for selecting IOTA participants, on the alternative approaches considered, including perceived advantages and disadvantages of our proposed participant selection approach relative to alternatives, and our responses:

Comment: Several commenters shared concerns about the participation selection method, with a commenter suggesting CMS would provide too short a notice of selection into the IOTA Model prior to the model start date and that this poses a challenge to smaller transplant programs. Additionally, a commenter shared a concern that the participant selection criteria highlights the significant variance in offer acceptance and transplant rates within DSAs, suggesting that it would be difficult to attribute outcome changes to the IOTA Model as a result.

Response: As described and finalized in section III.C.3.d(1) of this final rule, we proposed that CMS would notify IOTA participants of their selection to participate in the IOTA Model in a form and manner chosen by CMS, such as public notice and email, at least 3 months prior to the start of the model performance period. We believe this is in alignment with other Innovation Center models and an earlier notice would be provided if feasible. For these reasons, we are finalizing our proposal without modification.

Additionally, in section III.C.3.d(1) of this final rule, we described and finalized our approach for selecting IOTA participants to obtain a group of eligible kidney transplant hospitals that is representative of kidney transplant hospitals from across the country in terms of geography and kidney transplant volume. We proposed to stratify the DSAs into groups based on each DSA's Census Division and the total number of adult kidney transplants performed annually across all eligible kidney transplant hospitals in each DSA during the baseline years for the first PY. Selecting eligible kidney transplant hospitals from these groups of DSAs would ensure that the IOTA participants are representative of eligible kidney transplant hospitals from across the nation in terms of geography and the volume of adult kidney transplants.

A second aim of our proposal to select eligible kidney transplant hospitals from stratified groups of DSAs is to prevent distortions on the effects of the model's policies and features on outcomes. Our analysis of kidney transplant hospital data showed that selecting only some eligible kidney transplant hospitals within a selected DSA to participate in the IOTA Model may shift the supply of deceased donor organs from non-IOTA participants to IOTA participants within the same DSA. The resulting distortions would make it difficult to attribute changes in outcomes to the model and would limit its evaluability. As a result, we do not believe this would cause difficulty in attributing resulting impacts to the IOTA Model. For these reasons, we are finalizing our proposal without modification.

Comment: CMS received several comments and recommendations regarding participant selection for the IOTA Model. Specifically, commenters suggested CMS should modify the participant selection process in ways such as reconsidering the DSA as a quantifier, expanding the IOTA Model across all transplant programs, and providing eligible kidney transplant hospitals selected to participate in the IOTA Model more than a three-month notice prior to the start of the IOTA Model.

Response: We thank the commenters for their feedback and suggestions. We direct readers to section III.C.3.d(2) of this final rule for alternatives that we considered.

We believe that expanding accountability to kidney transplant hospitals and key stakeholders in the transplantation ecosystem for ESRD patients, aligns with the larger efforts across CMS and HRSA to improve performance and address disparities in kidney transplantation. As the most commonly transplanted organ, and its relationship with dialysis, of which Medicare is the primary payer, we believe focusing this model on kidney transplantation is prudent. Relatedly, as described in the proposed rule, we believe that it is necessary to include in the definition of kidney transplant those kidney transplants that occur in conjunction with other organ transplants to avoid creating a disincentive for multi-organ transplants within the IOTA Model (89 FR 43540).

Finally, regarding the comments we received about providing more than a three-month notice to eligible kidney transplant hospitals selected to participate in the IOTA Model, as described and finalized in section III.C.3.d(1) of this final rule, we proposed that CMS would notify IOTA participants of their selection to participate in the IOTA Model in a form and manner chosen by CMS, such as public notice and email, at least three months prior to the start of the model performance period. We believe this is in alignment with other Innovation Center models and an earlier notice would be provided if feasible. For these reasons, we are finalizing our proposal without modification at § 512.412(d).

Comment: Several commenters supported the use of stratified sampling in selecting IOTA participants. Specifically, several commenters supported the proposals to use DSAs, to group DSAs into Census Divisions, and to randomly select 50 percent of all eligible kidney transplant hospitals.

Response: We thank the commenters for their support.

Comment: In the context of the ETC Model, a commenter expressed concern that the use of stratified DSA sampling could penalize IOTA participants based on the DSA boundaries. Specifically, the commenter suggested that at times in the ETC Model, participants were penalized for circumstances that were largely based on zip code and compared to locales on the periphery of their DSA.

Response: As described and finalized in section III.C.3.c of this final rule, CMS will select approximately half of all DSAs nationwide using a stratified

sampling methodology, and all eligible kidney transplant hospitals in the selected DSAs will be required to participate in the IOTA Model. We proposed to stratify the DSAs into groups based on each DSA's Census Division and the total number of adult kidney transplants performed annually across all eligible kidney transplant hospitals in each DSA during the baseline years for the first PY (89 FR 43542). Within each Census Division group, we proposed to create two mutually exclusive groups of DSAs using the average number of adult kidney transplants performed annually across the baseline years for PY 1 (89 FR 43542). Selecting eligible kidney transplant hospitals from these groups of DSAs would ensure that the IOTA participants are representative of eligible kidney transplant hospitals from across the nation in terms of geography and the volume of adult kidney transplants. We recognize that kidney transplant hospitals in a DSA selected to participate in the IOTA Model could be adjacent to a DSA not selected to participate in the IOTA Model. The IOTA Model is looking to measure and test whether the provisions of the IOTA Model encourage more kidney transplants. We do not view this as potentially penalizing IOTA participants in close proximity to kidney transplant hospitals not participating in the IOTA Model. Rather, we believe this approach increases the ability to monitor performance improvements in metrics, such as an individual IOTA participants' transplant target or its organ offer acceptance rate ratio. It also helps us distinguish between DSAs and other similar geographical regions, ensuring accurate comparisons. For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters asserted that the stratified sampling methodology should not use DSAs, as it could restrict organ allocation, and that average number of kidney transplants in a DSA does not provide a true representation of kidney transplant hospitals.

Response: We thank the commenters for their feedback and suggestions. We direct readers to section III.C.3.d(2) of this final rule for a full discussion of the alternatives that we considered. For these reasons, we will be finalizing our proposal without modification.

Comment: Several commenters expressed their concerns with the proposed stratified sampling methodology, suggesting that the proposed stratification may advantage transplant programs close to the low-volume threshold. A commenter specifically suggested CMS should revisit this low volume threshold across PYs, since the expectation is that the volume of kidney transplants performed would progressively increase for kidney transplant hospitals selected to participate in the IOTA Model.

Response: We thank the commenters for their feedback and recommendations. As described and finalized in section III.C.5.c(1) of this final rule, we proposed that the low volume threshold to be 11 kidney transplants performed for the purposes of calculating the national growth rate. We also proposed this approach for calculating the national growth rate to account for and reflect the growth in organ procurement by OPOs that has occurred, indicating potential growth in the number of available organs.

Specifically, as described and finalized in section III.C.5.c(1) of this final rule, we will calculate the national growth rate by determining the percent increase or decrease of all kidney transplants furnished to patients 18 years of age or older during the relevant baseline years, as described and finalized in section III.C.3.c of this final rule. We direct readers to section III.C.5.c(1) of this final rule for a full discussion on the calculation of the national growth rate.

Finally, as described in section III.C.3.d(2) of the proposed rule, we expect that no additional participant selections will be made for the IOTA Model after its start date unless 10 percent or more of selected participants are terminated from the model during the model performance period. If this were to occur, we will address the selection of new participants in future rulemaking and we may revisit the low volume threshold of 11 adult kidney transplants performed annually in each of the baseline years. We would not extend the model performance period of the IOTA Model. If we were to add any new model participants, the IOTA participants would participate in the model until the end of model performance period, as described and finalized in section III.C.1.a of this final rule. For these reasons, we will be finalizing our proposal without modification.

Comment: Several commenters requested that CMS provide clarification on the stratified sampling methodology. Specifically, how CMS would randomly select one DSA, the distinction between high transplant volume or low transplant volume groups, and the threshold for dividing DSAs by transplant volume.

Response: We thank the commenters for their feedback. As described and finalized in section III.C.3.d(1) of this final rule, for groups within a Census Division group that contain an odd number of DSAs, CMS would randomly select one DSA from the group. Each of these individual selected DSAs would have a 50 percent probability of being selected for the IOTA Model. For groups within a Census Division group that contain an odd number of DSAs, CMS would randomly select one DSA from the group and determine that individual DSA's chance of selection for inclusion in the IOTA Model with 50 percent probability. Following this step, each group within a Census Division group would have an even number of DSAs.

As described and finalized in section III.C.3.d(1) of this final rule, CMS would then randomly select 50 percent of remaining DSAs in each group. CMS would then take a random sample, without replacement, of 50 percent of the remaining DSAs in each group (the groups being DSAs having higher numbers of adult kidney transplants across the baseline years and DSAs having lower numbers of adult kidney transplants across the baseline years) within each Census Division group. All of the eligible kidney transplant hospitals located within the selected DSAs would be required to participate in the IOTA Model. For these reasons, we are finalizing our proposal without modification.

Comment: Several commenters recommended that CMS stratify kidney transplant hospitals based on their size and reassess the threshold separating low-volume and high-volume kidney transplant hospitals.

Response: As described in section III.C.3.d(2) of the proposed rule, we considered alternatives to the proposed participant selection methods. We believe selecting model participants by DSA significantly mitigates behavior that would artificially inflate the model's effects on kidney transplant volume for the reasons described in the preceding section. OPOs associated with selected DSAs would be expected to benefit from consistency in rules across most or all of their transplant hospitals.

We considered alternative variables to create DSA groups for stratified sampling of DSAs. One alternative consideration included stratifying DSAs by annual adult kidney transplants per eligible transplant hospital in DSA (89 FR 43543). This and other variables were given consideration in the stratified selection approach, however, we opted to use the simpler stratified participant selection approach to provide greater transparency in the

model's participant selection approach. We direct readers to section III.C.3.d(2) of this final rule for a full discussion of alternative participant selection approaches and variables that we considered.

Additionally, as described and finalized in section III.C.3.d(1) this final rule, two groups within each Census Division group would be: (1) DSAs having higher numbers of adult kidney transplants across the baseline years; and (2) DSAs having lower numbers of adult kidney transplants across the baseline years. Since the average number of adult kidney transplants would be different across each DSA, each Census Division group would have a different cut off to create these two groups. We believe this is an appropriate distinction between low-volume and high-volume kidney transplant hospitals. For these reasons, we will be finalizing our proposal without modification.

Comment: Multiple commenters suggested that CMS should establish control groups within the same geographical area in order to increase the ability to monitor performance improvements and distinguish within DSAs to ensure accurate comparisons.

Response: We thank the commenters for their feedback and suggestions. As described and finalized in section III.C.3.c of this final rule, CMS would select approximately half of all DSAs nationwide using a stratified sampling methodology, and all eligible kidney transplant hospitals in the selected DSAs would be required to participate in the IOTA Model. Selecting eligible kidney transplant hospitals from these groups of DSAs would ensure that the IOTA participants are representative of eligible kidney transplant hospitals from across the nation in terms of geography and the volume of adult kidney transplants. As described and finalized in section III.C.3.d(1) of this final rule, within each Census Division group, we would create two mutually exclusive groups of DSAs using the average number of adult kidney transplants performed annually across the baseline years for PY 1. CMS would separate DSAs assigned to a Census Division group into two mutually exclusive groups of DSAs based on the average number of adult kidney transplants performed annually across the baseline years for PY 1. We believe this approach increases the ability to monitor performance improvements and distinguish within DSAs and similar geographical areas to ensure accurate comparisons. For these reasons, we will be finalizing our proposal without modification.

After consideration of the public comments we received, we are finalizing our proposed provisions for the sampling methodology, participant selection process, and notifying IOTA participants of their selection to participate in the IOTA Model at §§ 512.412(b), 512.412(c) and 512.412(d) without modification. We are also finalizing as proposed the definition of donation service area (DSA) at § 512.402, with a minor technical correction to include the complete cross reference to subpart G.

4. Patient Population and Attribution

a. Proposed Attributed Patient Population

We proposed that the following patients who are alive at the time CMS conducts attribution would be attributed to an IOTA participant: (1) A kidney transplant waitlist patient, as defined in section III.C.4.a of this final rule, regardless of payer type and waitlist status, who is alive, 18 years of age or older, and is registered on a waitlist, as defined in section III.C.4.a of this final rule, to one or more IOTA participants, as identified by the OPTN computer match program (''IOTA waitlist patient''); and (2) A kidney transplant patient who receives a kidney transplant at the age of 18 years or older from an IOTA participant at any time during the model performance period (''IOTA transplant patient''). These patients would be referred to as IOTA waitlist patients and IOTA transplant patients, respectively, for purposes of assessing each IOTA participant's performance across the achievement domain, efficiency domain, and quality domain as discussed in section III.C.5 of this final rule. IOTA waitlist patients and IOTA transplant patients would factor into the model's performance-based payments to IOTA participants.

For the purpose of this model, we proposed to define ''waitlist'' as a list of transplant candidates, as defined in 42 CFR 121.2, registered to the waiting list, as defined in § 121.2, and maintained by a transplant hospital in accordance with 42 CFR 482.94(b). We proposed to define ''kidney transplant waitlist patient'' as a patient who is a transplant candidate, as defined in § 121.2, and who is registered to a waitlist for a kidney at one or more kidney transplant hospitals.

We understand that many patients on the waiting list are registered at multiple transplant hospitals. Therefore, we proposed attributing each of these waitlisted patients to every IOTA participant where they are registered on a waitlist during a given month in the applicable quarter. However, ''kidney transplant patient,'' defined as a patient who is a transplant candidate, as defined in § 121.2, and received a kidney transplant furnished by a kidney transplant hospital, regardless of payer type, would be attributed to the IOTA participant that furnished the kidney transplant.

We proposed attributing kidney transplant waitlist patients and kidney transplant recipients to IOTA participants for two reasons. First, we believe that by attributing these patients to IOTA participants it would ensure the full population of potential and actual kidney transplant candidates is represented when measuring participant performance. The waiting list captures most candidates except some living donor recipients. Transplant recipients include those who received deceased or living donor transplants. Second, because CMS is proposing to hold IOTA participants accountable for furnishing kidney organ transplants; focusing on kidney transplant waitlist patients and kidney transplant patients, and attributing them to IOTA participants, aligns with the model's goals of improving access to, and quality of, kidney transplantation, including post-transplant.

CMS proposed to determine an IOTA participant's performance across the achievement domain, efficiency domain, and quality domain based on all IOTA waitlist patients and IOTA transplant patients, regardless of payer type, as described in section III.C.5 of this final rule. That is, an IOTA participant's performance in terms of both Medicare beneficiaries and non-Medicare patients would be used to determine whether the IOTA participant would receive an upside risk payment from CMS, or owe a downside risk payment to CMS. As described in section III.C.6.c(2) of this final rule, demand for kidney transplants far exceeds supply, raising concerns that if the IOTA Model were limited to Medicare beneficiaries only, the model may inadvertently incentivize inappropriate diversion of donor organs to Medicare beneficiaries to improve their performance in the model, thereby limiting access to non-Medicare beneficiaries and potentially disincentivizing pre-emptive kidney transplants for patients not already covered by Medicare because their CKD has not progressed to ESRD. We believe that the change in care patterns that IOTA participants may undertake to be successful in the IOTA Model are unlikely to apply solely to Medicare beneficiaries under their care.

We considered limiting IOTA waitlist patients and IOTA transplant patients to Medicare beneficiaries only, as Medicare covers more than 50 percent of all kidney transplants from both deceased and living donors. However, we believe it is necessary to include all patients, regardless of payer type, in the IOTA participant's performance calculations to protect against unintended consequences and problematic financial incentives. Moreover, the group of eligible waitlist and transplant patients that would be attributed to each IOTA participant is already relatively small, both in terms of transplant candidates and transplant recipients. Limiting the IOTA Model performance assessment, as described in section III.C.5.b of this final rule, to Medicare beneficiaries would further limit the patient sample size, potentially affecting our ability to detect changes in performance due to model payments. Therefore, we proposed that the IOTA Model reflect both Medicare beneficiaries and non-Medicare patients for performance assessment, with Medicare beneficiaries just being a subset of the patient population attributed to each model participant.

We sought public comment on our proposals to include: (1) all kidney transplant waitlist patients, regardless of payer type and waitlist status, who are alive, 18 years of age or older, and registered on a waitlist to an IOTA participant, as identified by the OPTN computer match program; and (2) all kidney transplant patients who receive a kidney transplant, at 18 years of age or older, from an IOTA participant at any time during the model performance period, in each IOTA participant's population of attributed patients. We also sought public comment on our proposal to attribute IOTA waitlist patients and IOTA transplant patients, respectively, to IOTA participants for the purposes of assessing each IOTA participant's performance across the achievement domain, efficiency domain, and quality domain, and to determine performance-based payments to and from IOTA participants.

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

Comment: We received several comments in support for the proposed attributed patient population, including the all-payer attribution approach and to allow patients to have multiple attributions when on the waitlist for one or more transplant hospitals, as this provision ensures the most patients can benefit from the model.

Response: We thank the commenters for their support.

Comment: We received a comment requesting CMS clarify if multi-organ transplants would be counted the same as single organ kidney transplants.

Response: We thank the commenter for their feedback. As described in section III.B.3.c of the proposed rule, the vast majority of kidney transplants are performed alone. However, we believe that it is necessary to include in the definition of kidney transplant those kidney transplants that occur in conjunction with other organ transplants to avoid creating a disincentive for multi-organ transplants within the IOTA Model. As defined at § 512.402, kidney transplant means the procedure in which a kidney is surgically transplanted from a living or deceased donor to a transplant recipient, either alone or in conjunction with any other organ(s).

Comment: We received a comment suggesting CMS should monitor for unintended consequences, such as systemic biases, as a result of including all payer types among attributed patients.

Response: We thank the commenter for their suggestion. We direct readers to comment responses noted previously for further discussion. For these reasons, we are finalizing our proposal without modification.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing these provisions at § 512.414 with slight modification. Specifically, we are modifying the regulatory text at § 512.414(a)(1)(iii) to specify determining performance-based payments paid to or by IOTA participants. We did not receive any comments on the proposed definition of IOTA waitlist patient, kidney transplant waitlist patient, kidney transplant patient or waitlist and therefore are finalizing these definitions without modification at § 512.402. We are also making a minor technical correction to the proposed definition of IOTA transplant patient at § 512.402 to update the cross reference. Specifically, we are removing the cross reference to § 512.412(b)(2) and replacing it with § 512.414(b)(2). As such, we are finalizing the definition of IOTA transplant patient at § 512.402 to mean a kidney transplant patient who receives a kidney transplant at the age of 18 years of age or older from an IOTA participant at any time during the model performance period and meets the criteria set forth in § 512.414(b)(2).

b. Patient Attribution Process

As described in section III.C.4.a of this final rule, we proposed to define ''attribution'' as the process by which CMS identifies patients for whom each IOTA participant is accountable during the model performance period. CMS would identify and assign a set of Medicare and non-Medicare patients to the IOTA participant through attribution. We proposed to define ''attributed patient'' as an IOTA waitlist patient or an IOTA transplant patient, as described in section III.C.4.a of this final rule. We proposed that a patient may not opt out of attribution to an IOTA participant under the model.

Section III.C.4.b(1) of this final rule outlines in more detail the attribution criteria to identify attributable kidney transplant waitlist patients and kidney transplant patients during initial attribution, quarterly attribution, and at annual attribution reconciliation using Medicare claims data, Medicare administrative data, and OPTN data. In advance of the model start date, we proposed to attribute patients to IOTA participants through an initial attribution process described in section III.C.4.b(2) of this final rule; quarterly attribution would be conducted thereafter to update the patient attribution list, as described in section III.C.4.b(3) of this final rule, to include the dates in which patient attribution changes occur. After the fourth quarter of each PY, we proposed to finalize each IOTA participant's annual attribution reconciliation list for that PY, including removing certain attributed patients, as described in section III.C.4.b(4) of this final rule. We proposed that once a patient is attributed to an IOTA participant, that attributed patient would remain attributed to the IOTA participant for the duration of the model, unless the patient is removed from the IOTA participant's list of attributed patients during the annual attribution reconciliation process, as described in section III.C.4.b(4) of this final rule.

We also considered proposing that once a patient is attributed to an IOTA participant, either through the initial attribution process or through quarterly attribution, that the patient would remain attributed only through the end of the PY. Initial attribution would then occur prior to the beginning of each PY. However, we choose to align with the attribution processes of our other kidney models to simplify operations.

We proposed to identify kidney waitlist patients and kidney transplant patients using SRTR data, OPTN data, Medicare claims data, and Medicare administrative data.

We sought comment on our patient attribution process proposals and alternatives considered.

The following is a summary of the comments received on our proposed patient attribution process proposals and alternatives considered and our responses:

Comment: We received several comments requesting clarity from CMS on certain categories of attributed patients, as well as seeking clarity on what CMS defines as an attributed patient. Specifically, we received comments requesting CMS to clarify if any patients are excluded from calculations related to the IOTA Model in the context of kidney/pancreas candidates and others such as those with a high panel reactive antibody test, re-transplanted patients, or safety-net kidney recipients.

Response: As described and finalized in section III.C.4.b of this final rule, we define attributed patient as an IOTA waitlist patient or an IOTA transplant patient. As described and finalized in section III.C.4.a of this final rule, an IOTA waitlist patient is a kidney transplant waitlist patient, as defined and finalized in section III.C.4.a of this final rule, regardless of payer type and waitlist status, who is alive, 18 years of age or older, and is registered on a waitlist, as defined and finalized in section III.C.4.a of this final rule, to one or more IOTA participants, as identified by the OPTN computer match program; and an IOTA transplant patient is a kidney transplant patient who receives a kidney transplant at the age of 18 years or older from an IOTA participant at any time during the model performance period.

Additionally, as described and finalized in section III.C.5.d(1)(a) of this final rule, we proposed to use and calculate the OPTN organ offer acceptance rate ratio in accordance with OPTN's measure specifications and SRTR's methodology as the metrics that would determine IOTA participants' performance on the efficiency domain outlined in equation 1 in paragraph (b)(1) of § 512.426. As it pertains to kidney/pancreas candidates, included in this organ offer acceptance ratio are offers to candidates on a single organ waitlist (except for kidney/pancreas candidates that are also listed for kidney alone). Excluded from this measure are offers to multi-organ candidates (except for kidney/pancreas candidates that are also listed for kidney alone).

In addition, paragraph (b)(1) at § 512.428 describes the composite graft survival rate equation used in determining the IOTA participant's quality domain score. As it pertains to kidney/pancreas candidates and re-transplant candidates, CMS excludes them from the numerator when calculating the composite graft survival rate.

As proposed, we do not exclude any patients with high panel reactive antibody tests or safety-net kidney recipients from IOTA Model measures. For these reasons, we are finalizing our proposal without modification.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing the patient attribution process at § 512.414(a) and the definitions of attribution and attributed patient at § 512.402 as proposed without modification.

(1) Attribution and De-attribution Criteria

(i) IOTA Waitlist Patient Attribution

We proposed that kidney transplant waitlist patients would be attributed as IOTA waitlist patients to one or more IOTA participants based on where the patient is registered on a kidney transplant waitlist, regardless of payer type and waitlist status, as identified by the OPTN computer match program. We proposed that CMS would conduct attribution on a quarterly basis, before each quarter of the model performance period. CMS is proposing to attribute a kidney transplant waitlist patient as an IOTA waitlist patient to an IOTA participant if the patient meets all of the following criteria:

- The patient is registered to one or more IOTA participant's kidney transplant waitlist during a month in the applicable quarter.
- The patient is 18 years or older at the time of attribution.
- The patient is alive at the time of attribution.

For purposes of attributing IOTA waitlist patients to IOTA participants, the proposed criteria must be met on the date that CMS runs attribution, as described in section III.C.4.b(1)(i) of this final rule.

As described in section III.C.4.b(1) of this final rule, a kidney transplant waitlist patient may be registered to more than one waitlist, which is why we proposed to attribute kidney transplant waitlist patients as IOTA waitlist patients to IOTA participants in a way that accurately reflects their waitlist registrations. A kidney transplant hospital should be actively engaged in coordinating the transplant process for kidney transplant waitlist patients on their waitlist, as they are responsible for accepting donor organs and furnishing transplants. As such, if a kidney transplant waitlist patient is registered on the waitlist of multiple IOTA participants, CMS would attribute that kidney transplant waitlist patient as an IOTA waitlist patient to all of the IOTA participants that have the kidney transplant waitlist patient on their waitlists.

We alternatively considered limiting IOTA waitlist patient attribution to only one IOTA participant based on ''active'' waitlist status. That is, the IOTA waitlist patient would be attributed to each IOTA participant where the patient is registered to a kidney transplant waitlist with an ''active'' status in a given quarter. A kidney transplant hospital designates patients on its waitlist with an ''active'' status to signal their readiness to receive a donor kidney offer when one becomes available. However, we anticipate that there would be operational challenges if CMS were to base patient attribution on waitlist ''active'' status, as doing so would require real-time and accurate information regarding each patient's waitlist status. There may be a time delay when changing a waitlist status from provisionally inactive to active once minor issues have been resolved. A kidney transplant waitlist patient may be made inactive or ineligible to receive an organ offer if, for example, they have an incomplete transplant evaluation to assess medical readiness, their BMI exceeds the transplant hospital's established threshold, due to infection or patient choice, or because of complications presented by other medical issues. Additionally, due to our inability to recognize differences in the contributions between kidney transplant hospitals in maintaining a patient's transplant readiness, we believe attributing kidney transplant waitlist patients as IOTA waitlist patients to all the IOTA participants where a kidney transplant waitlist patient is registered is the most appropriate approach to IOTA waitlist patient attribution, regardless of waitlist status.

As indicated in section III.C.3.c of this final rule, we are only proposing to include non-pediatric facilities as eligible participants in the IOTA Model. In alignment with this proposal, we proposed to exclude pediatric patients under 18 years of age from the population of attributed patients. According to national data from the OPTN, children under the age of 18 make up a small proportion of the kidney transplant candidates registered on the waiting list. However, pediatric patients have greater access to both deceased and living donor kidney transplant relative to adults. Pediatric patients under 18 years of age are also infrequently the recipient of organs at

high risk for non-use.[187] Thus, CMS did not propose to include pediatric patients under the age of 18 as part of the population that would be identified and attributed to IOTA participants. We alternatively considered including pediatric patients under the age of 18 in the IOTA Model patient population, but believe focusing on adults, given their unique challenges accessing kidney transplants, is a priority.

The waiting list often has a delay between when a patient's waitlist status changes and when that change is reflected in the data. For example, patients who have died are ineligible for transplant and must be removed from the waiting list, but there may be a time delay between a patient's death and their removal. Thus, we proposed to limit IOTA waitlist patient attribution to patients who are alive at the time of attribution.

We sought comment on our proposed criteria for identifying and attributing kidney transplant waitlist patients to one or more IOTA participants and alternatives considered.

The following is a summary of the comments received on our proposed criteria for identifying and attributing kidney transplant waitlist patients to one or more IOTA participants and alternatives considered and our responses:

Comment: A commenter recommended CMS change the proposed definition of a pediatric transplant to include a transplant performed on a patient who may be 18 years or older, but was listed on the kidney transplant waiting list prior to age 18. Specifically, a commenter recommended this change in definition because the commenter thought that its preferred definition would satisfy existing industry standards and better reflect the nature of a pediatric patient who may not receive a transplant until after turning 18 years old, but could remain under the care of a pediatric transplant program.

Response: We thank the commenter for their suggestion; however, we disagree as we did not propose to define a pediatric transplant. At 89 FR 43544 of the proposed rule, we proposed to define an IOTA transplant patient as a kidney transplant patient who receives a kidney transplant at the age of 18 years or older from an IOTA participant at any time during the model performance period. As we are including only non-pediatric facilities in our definition of eligible kidney transplant hospitals, as described and finalized in section III.C.3.c of this final rule, we believe that those that are listed prior to the age of 18 under the care of a pediatric facility would not be included in our definition of an IOTA transplant patient. Therefore, we will be finalizing our proposed definition of IOTA transplant patient without modification.

Comment: A commenter expressed support for CMS's proposal to attribute kidney transplant waitlist patients to one or more IOTA participants based on where the patient is registered on a kidney transplant waitlist.

Response: We thank the commenter for their support.

Comment: We received a comment voicing concern with the proposed IOTA waitlist patient and patient attribution process in that it could create competition among transplant hospitals due to the cross-listing of patients.

Response: We thank the commenter for their feedback. As described in section I.B.2.a of this final rule, we proposed that the IOTA Model would test whether performance-based incentive payments paid to or owed by participating kidney transplant hospitals increase access to kidney transplants for patients with ESRD while preserving or enhancing the quality of care and reducing Medicare expenditures. Specifically, we proposed to test whether performance based incentives (including both upside and downside risk) for participating kidney transplant hospitals can increase the number of kidney transplants (including both living donor and deceased donor transplants) furnished to ESRD patients, encourage investments in care processes and patterns with respect to patients who need kidney transplants, encourage investments in value-based care and improvement activities, and promote kidney transplant hospital accountability by tying payments to value. We believe a cross-listing of patients through the IOTA waitlist patient and patient attribution process is beneficial for patients and increases their likelihood of receiving a transplant. For these reasons, we are finalizing our proposal without modification.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed criteria for identifying and attributing kidney transplant waitlist patients as IOTA waitlist patients to one or more IOTA participants at § 512.414(b)(1) without modification.

(ii) IOTA Transplant Patient Attribution

We proposed that kidney transplant patients would be attributed as IOTA transplant patients to the IOTA participant that furnished a kidney transplant during the model performance period, if they meet the following criteria:

- The patient was 18 years of age or older at the time of their transplant; and
- The patient was alive at the time of attribution.

We note that an IOTA transplant patient who experiences transplant failure and is then de-attributed from an IOTA participant, as described in section III.C.4.b(1)(iii) of this final rule, could become attributed to an IOTA participant again at any point during the model performance period if they rejoined a kidney transplant waitlist for, or received a kidney transplant from, any IOTA participant and satisfied all of the criteria for attribution as described in section III.C.4.b(1)(i) or section III.C.4.b(1)(ii) of this final rule.

We proposed to attribute kidney transplant patients to the IOTA participant that furnished the transplant to hold the IOTA participant accountable for patient transplant and post-transplant outcomes. We alternatively considered attributing kidney transplant patients based on the plurality of post-transplant services, as identified in Medicare claims, because it would still result in attributing kidney transplant patients to only one IOTA participant and would base attribution on where the majority of services were furnished. We recognize that patients may choose to receive their pre-and post-transplant care from multiple IOTA participants in addition to the IOTA participant that performed their kidney transplant. However, the model's incentives do not support shifting accountability for post-transplant outcomes away from the IOTA participant that furnished the transplant. We believe that the IOTA participant that performed the transplant should remain accountable for any surgery related outcomes, both successes and failures.

We proposed not to attribute patients who are younger than 18 years of age at the time of their kidney transplant or who are deceased at the time of attribution due to the same reasons described in section III.C.4.b(1)(i) of this final rule.

We sought comment on our proposed criteria for identifying and attributing kidney transplant patients as IOTA

[187] 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.*

transplant patients to the IOTA participant that furnished their kidney transplant during the model performance period. We also sought comment on the alternative considered.

We received no comments on this proposal and therefore are finalizing the provisions for our proposed criteria for identifying and attributing kidney transplant patients as IOTA transplant patients to the IOTA participant that furnished their kidney transplant during the model performance period at § 512.414(b)(2) as proposed without modification.

(iii) De-Attribution Criteria

We proposed that CMS would only de-attribute attributed patients from an IOTA participant during annual attribution reconciliation, as described in section III.C.4.b(4) of this final rule. We proposed that CMS would de-attribute any attributed patient from an IOTA participant that meets any of the following criteria as of the last day of the PY being reconciled, in accordance with the annual attribution reconciliation list as described in section III.C.4.c of this final rule:

- The IOTA waitlist patient was not registered on an IOTA participant's kidney transplant waitlist on the last day of the PY being reconciled.
- The IOTA waitlist patient died at any point during the PY. We proposed that an IOTA waitlist patient who has died during the PY would be removed from the list of attributed IOTA waitlist patients effective on the last day of the PY that the death occurred.
- The IOTA transplant patient has died at any point during the PY. We proposed that an IOTA transplant patient who has died during the PY would be de-attributed from the list of attributed IOTA transplant patients effective on the last day of the PY that the death occurred.
- The IOTA transplant patient's kidney failed during the PY, and the patient is not included on the IOTA participant's waitlist. We proposed that an IOTA transplant patient who experiences transplant failure at any point during the PY and does not rejoin an IOTA participant's kidney transplant waitlist or receive another transplant from an IOTA participant before the last day of the same PY would be listed as de-attributed in the annual attribution reconciliation list. This IOTA transplant patient would no longer be attributed to the IOTA participant effective the last day of the PY in which the IOTA transplant patient's kidney transplant has failed.

We sought comment on our proposed methodology and criteria for identifying and de-attributing attributed patients from an IOTA participant.

The following is a summary of the comments received on our proposed methodology and criteria for identifying and de-attributing attributed patients from an IOTA participant and our responses:

Comment: A commenter expressed support for CMS's proposed de-attribution criteria.

Response: We thank the commenter for their support.

Comment: A commenter requested more information about the source of the data that would be used to verify the graft loss or death.

Response: We thank the commenter for their feedback. As noted in section V.C of the proposed rule, the SRTR data source includes data on all transplant donors, candidates, and recipients in the U.S. As described in the proposed rule, section III.C.4.b of the proposed rule outlines our proposal to use of SRTR data, OPTN data, Medicare claims data, and Medicare administrative data for the purposes of the IOTA Model. Additionally, section III.C.5.e(1) of this final rule describes and finalizes our proposal to use of OPTN follow-up forms to identify graft failure and re-transplant dates. We acknowledge that for the purposes of measuring graft survival using OPTN data, use of either concept would generate the same outcome measurement because OPTN data identify graft status as either functioning or failed. However, we aim to convey the importance of ongoing management to preserve the health of the transplanted graft and the health and quality of life of the attributed patients.

Finally, as described and finalized in section III.C.13.a of this final rule, we proposed that CMS, or its approved designees, would conduct compliance monitoring activities to ensure compliance by the IOTA participant and IOTA collaborators with the terms of the IOTA Model, including to understand IOTA participants' use of model-specific payments and to promote the safety of attributed patients and the integrity of the IOTA Model. One proposed monitoring activity would include audits of claims data, quality measures, medical records, and other data from the IOTA participant and its IOTA collaborators. For these reasons, we are finalizing our proposal without modification.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed methodology and criteria for identifying and de-attributing attributed patients from an IOTA participant at § 512.414(b)(3), as proposed without modification.

(2) Initial Attribution

We proposed that before the model start date, CMS would conduct an ''initial attribution'' to identify and prospectively attribute waitlist patients to an IOTA participant pursuant to § 512.414. The list of IOTA waitlist patients identified through initial attribution, namely the initial attribution list, would prospectively apply to the first quarter of PY 1, effective on the model start date. The purpose of this initial attribution list would be to prospectively provide IOTA participants with a list of their IOTA waitlist patients for the upcoming quarter.

We considered attributing patients to IOTA participants at different points in time, such as the day that a kidney transplant waitlist patient was added to the IOTA participant's kidney transplant waitlist, or the day that a kidney transplant patient received their kidney transplant. This approach would be more precise than considering all attributed patients to be attributed as of the start of the quarter. However, due to the limitations of data sources and the frequency with which these data are updated, we did not see this as a viable alternative.

We sought comment on our proposal to conduct initial attribution before the model start date and alternatives considered.

We received no comments on this proposal and therefore are finalizing the provisions as proposed without modification at § 512.414(c)(1) and the definition of initial attribution at § 512.402, without modification.

(3) Quarterly Attribution

We proposed that CMS would attribute patients to IOTA participants in advance of each quarter, after initial attribution, and distribute a ''quarterly attribution list'' to each IOTA participant that includes all their attributed patients, including newly attributed patients, on a quarterly basis throughout the model performance period, except in the event of termination as described in section III.C.16(b) of this final rule.

We considered monthly attribution for more frequent updates to the initial attribution list, but believe it would be operationally burdensome. We also considered annual attribution for less frequent updates to the initial attribution list, which would be less operationally burdensome than monthly or quarterly attribution. Annual attribution is common in other

Innovation Center models and CMS programs where the participant is managing total cost of care for a population. The benefits of annual attribution would include prospectively providing participants a stable list of patients for whom they would be held accountable, and, as the process would occur only once a year, would be associated with lower administrative burden. The downside of annual attribution, however, is that IOTA participants would have less frequent updates and understanding of their attributed population, potentially making it hard to plan and budget accordingly. We do not believe annual attribution would be appropriate for the IOTA Model's goal of improving access to kidney transplants and quality of care for a patient population that changes frequently. For example, kidney transplant hospitals add patients to their kidney transplant waitlist throughout the year. Were we to limit attribution to once a year, kidney transplant waitlist patients added during the year would not be attributed to an IOTA participant until the following year, delaying our ability to meet the minimum number of patients required to evaluate a model test. As such, we believe more frequent attribution would be necessary.

We sought comment on our proposal to conduct attribution on a quarterly basis during the model performance period and on the alternatives considered.

The following is a summary of the comments received on our proposal to conduct attribution on a quarterly basis during the model performance period and on the alternatives considered and our responses:

Comment: Several commenters voiced their support for the proposed quarterly attribution provisions, stating that it would ensure accuracy and fairness.

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 proposed quarterly attribution provisions at § 512.414(c)(2), without modification. We received no comments on the proposed definition of quarterly attribution list and there are finalizing this definition without modification at § 512.402.

(4) Annual Attribution Reconciliation

We proposed that after the end of each PY, CMS would conduct annual attribution reconciliation. We proposed to define ''annual attribution reconciliation'' as the yearly process by which CMS would: (1) create each IOTA participant's final list of attributed patients for the PY being reconciled by retrospectively de-attributing from each IOTA participant any attributed patients that satisfied a criterion for de-attribution pursuant to § 512.414(c); and (2) create a final list of each IOTA participant's attributed patients who would remain attributed for the PY being reconciled, subject to the attribution criteria in §§ 512.414(b)(1) and (2). For the purposes of this model, we proposed to define ''annual attribution reconciliation list'' as the final cumulative record of attributed patients that would be generated annually for whom each IOTA participant was accountable for during the applicable PY.

For example, after PY 1, CMS would rerun attribution for the entire PY to finalize the list of attributed patients that met the criteria specified in sections III.C.4.b(1) and (2) of this final rule. Once the fourth quarter is complete, CMS would use the fourth quarter attribution list to determine and de-attribute any attributed patients that meet a criterion for de-attribution, as described in section III.C.4.b(1)(iii) of this final rule, from the IOTA participant, as described in section III.C.4.b(1)(iii) of this final rule, and remove those attributed patients from the quarterly attribution list to create the annual attribution reconciliation list. Before the second quarter of the following PY, CMS would distribute the annual attribution reconciliation list to IOTA participants. We proposed that these lists, at a minimum, would identify each attributed patient, identify reasons for de-attribution in the previous PY, and the dates in which attribution began, changed, or ended, where applicable.

We sought comment on our proposal to conduct annual attribution reconciliation.

The following is a summary of the comments received on our proposal to conduct annual attribution reconciliation and our responses:

Comment: Several commenters expressed support for CMS's proposal to conduct annual attribution reconciliation.

Response: We thank the commenters for their support.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing the policy for annual attribution reconciliation as proposed in § 512.414(c)(3), with a minor technical correction to update the cross references in the regulation text at §§ 512.414(c)(3)(ii)(A) and 512.414(c)(3)(ii)(C–F). We are also finalizing the definitions of annual attribution reconciliation and annual attribution reconciliation list at § 512.402 without modification.

c. IOTA Patient Attribution Lists

We proposed that no later than 15 days prior to the start of the first model performance period, CMS would provide the IOTA participant the ''initial attribution list.'' For the purposes of the model, we proposed to define ''days'' as calendar days, as defined in 42 CFR 512.110, unless otherwise specified by CMS. On a quarterly basis thereafter, CMS would provide the IOTA participant the ''quarterly attribution list'' no later than 15 days prior to the start of the next quarter. The annual attribution reconciliation list for a given PY would be provided to the IOTA participants after the conclusion of the PY, before the second quarter of the following PY.

We proposed that the initial, quarterly, and annual attribution reconciliation lists would be provided in a form and manner determined by CMS.

We sought comment on our proposed attribution list policies.

The following is a summary of the comments received on our proposed attribution list policies and our responses:

Comment: Several commenters requested that CMS provide the patient attribution lists be provided well in advance of the performance period to allow IOTA participants to prepare accordingly and assess performance impacts. Specifically, a commenter suggested providing attribution lists at least one quarter in advance of the start of the performance period.

Response: We thank the commenters for their feedback. As described and finalized in section III.C.4.c of this final rule, we proposed that 15 days prior to the start of the first model performance period, CMS would provide the IOTA participant the initial attribution list. On a quarterly basis thereafter, CMS would provide the IOTA participant the quarterly attribution list no later than 15 days prior to the start of the next quarter. The annual attribution reconciliation list for a given PY would be provided to the IOTA participants after the conclusion of the PY, before the second quarter of the following PY. This sequence for patient attribution lists follows the same pattern as other Innovation Center models—such as the KCC Model—and, therefore, we are finalizing this provision without modification.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing, as proposed, our provisions at §§ 512.414(c)(1)(ii),

512.414(c)(2)(ii), 512.414(c)(3)(ii) and the definition of days at § 512.402 without modification.

5. Performance Assessment

a. Goals and Proposed Data Sources

As described in section III.B. of the proposed rule, CMS and the OPTN each have roles in assessing the performance of kidney transplant hospitals. CMS' regulations in 42 CFR part 482 subpart E require certain conditions of participation for kidney transplant hospitals to receive approval to perform Medicare transplant services. Under 42 CFR part 121, the OPTN is required to implement a peer review process by which OPOs and transplant hospitals are periodically reviewed for compliance with the bylaws of the OPTN and the OPTN final rule (63 FR 16332). The OPTN MPSC is charged with performing these evaluations; including the identification of threats to patient safety and public health.[188]

As described in section III.C.5.a. of the proposed rule, CMS and the OPTN have each acknowledged the limitations of transplant hospital performance assessment based on the one-year patient and transplant survival measure alone. In 2018, CMS eliminated its assessment of one year patient and transplant survival for the purposes of transplant hospital re-approval in the final rule, ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51732), leaving assessment of the one year patient and transplant survival measure only for initial Medicare approval, due to concerns that the measure was causing conservative behavior in transplant hospitals.[189] In 2021, the OPTN disseminated a proposal to enhance the MPSC's performance monitoring process by expanding the number of measures used to identify transplant hospital underperformance.[190] In that proposal, the OPTN acknowledged the potential for transplant hospital risk aversion due to the MPSC's evaluations of performance based on the one year patient and transplant survival metric alone and proposed transplant hospital assessment based on a holistic set of measures encompassing aspects of care across the transplant journey.[191]

As described in section III.C.5.a. of the proposed rule, strengthening and improving the performance of the organ transplantation system is a priority for HHS, including CMS and HRSA. In accordance with this priority and joint efforts with HRSA, the IOTA Model would aim to improve performance and equity in kidney transplantation by testing whether performance-based payments to IOTA participants increases access to kidney transplants for kidney transplant waitlist and kidney transplant patients attributed to IOTA participants in the model, thereby reducing Medicare program expenditures while preserving or enhancing quality of care. For the IOTA Model, we proposed a broader set of metrics which aligns with the trends that we believe would encourage IOTA participants to meet the model goals as described in section III.A of this final rule.

As described in section III.C.5.a of the proposed rule, the IOTA Model would assess performance on a broad set of metrics that were selected to align with all of the following model goals:

- Increase number of, and access to, kidney transplants.
- Improve utilization of available deceased donor organs.
- Support more donors through the living donation process.
- Improve quality of care and equity.

In section III.C.5.a of the proposed rule, we proposed using Medicare claims and administrative data about beneficiaries, providers, suppliers, and data from the OPTN, which contains comprehensive information about transplants that occur nationally, to measure IOTA participant performance in the three model domains: (1) achievement domain; (2) efficiency domain; and (3) quality domain. Medicare administrative data refers to non-claims data that Medicare uses as part of regular operations. This includes information about beneficiaries, such as enrollment information, eligibility information, and demographic information. Medicare administrative data also refers to information about Medicare-enrolled providers and suppliers, including Medicare enrollment and eligibility information, practice and facility information, and Medicare billing information.

We solicited comment on our proposal for selecting performance metrics and performance domains. We also solicited comment on our proposed use of Medicare claims data, Medicare administrative data, and OPTN data to calculate the performance across the three proposed domains, as described in section III.C.5. of this final rule.

The following is a summary of comments received on our proposal for selecting performance metrics and performance domains, in addition to our proposed use of Medicare claims data, Medicare administrative data, and OPTN data to calculate the performance across the three proposed domains and our responses:

Comment: A commenter conveyed their concern that the OPO and transplant performance metrics are misaligned and as a result will minimize the impact of the IOTA Model.

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 believe that HRSA and CMS do not have misaligned goals.

Comment: A few commenters stated that they believe the three domains will lead to a successful solution and are acceptable.

Response: We appreciate the commenters' support. We believe that including the achievement, efficiency and quality domain are an ideal combination to ensure that while IOTA participants are increasing kidney transplants, we are also monitoring acceptance patterns and post-transplant outcomes.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing the proposed provisions for selecting performance metrics and performance domains at § 512.422(a), without modification. We did not receive any comments regarding

[188] *https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/.*

[189] *https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/* and Burden Reduction. **Federal Register**. *https://www.federalregister.gov/d/2018-19599/p-215.*

[190] *https://optn.transplant.hrsa.gov/media/4777/transplant_program_performance_monitoring_public_comment_aug2021.pdf.*

[191] *Ibid.*

our proposed use of Medicare claims data, Medicare administrative data, and OPTN data to calculate the performance across the three proposed domains and therefore are finalizing this provision without modification at § 512.422(b).

b. Method and Scoring Overview

In accordance with our proposed goals of the IOTA performance assessment, as described in section III.C.5.a of the proposed rule, we proposed to assess performance across three domains: (1) achievement domain; (2) efficiency domain; and (3) quality domain. We proposed to use one or more metrics within each domain to assess IOTA participant performance. We proposed at § 512.422(a)(2) that CMS would assign each set of metrics within a domain a maximum point value, with the total possible points awarded to an IOTA participant being 100 points. We proposed to define ''final performance score'' as the sum total of the scores earned by the IOTA participant across the achievement domain, efficiency domain, and quality domain for a given PY. We also proposed that the combined sum of total possible points would determine whether and how the IOTA Model performance-based payments, as described and finalized in section III.C.6.c of this final rule, would apply and be calculated. We proposed the following point allocations for each of these three domains:

- The achievement domain would make up 60 of 100 maximum points. The achievement domain would measure the number of kidney transplants performed relative to a participant-specific target, as described in section III.C.5.c of the proposed rule. The achievement domain would represent a large portion (60 percent) of the maximum total performance score. We weighted the achievement domain performance score more than the efficiency and quality domain because we believe it aligns with the primary goal of the IOTA Model, to increase the overall number of kidney transplants. Additionally, because increasing the number of kidney transplants performed is the primary goal of the model, we believe weighing performance on this measure more than the efficiency domain and quality domain is necessary to directly incentivize participants to meet their target.
- The efficiency domain would make up 20 of 100 maximum points. The efficiency domain would measure performance on a kidney organ offer acceptance rate ratio, as described in section III.C.5.d of the proposed rule.
- The quality domain would make up 20 of 100 maximum points. As described in section III.C.5.e. of the proposed rule, the quality domain would measure performance on a set of quality metrics, including post-transplant outcomes, and on three proposed quality measures—CollaboRATE Shared Decision-Making Score, Colorectal Cancer Screening, and 3-Item Care Transition Measure.

We believed that many prospective IOTA participants may already be familiar with the approach of assigning points up to a maximum in multiple domains. This structure is similar to other CMS programs, including the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program. For MIPS, we assess the performance of MIPS eligible clinicians (as defined in 42 CFR 414.1305) across four performance categories—one of which is quality—and then determine a positive, neutral, or negative MIPS payment adjustment factor that applies to the clinician's Medicare Part B payments for professional services. Similar to MIPS, we proposed that the IOTA Model would use a performance scoring scale from zero to 100 points across performance domains, and apply a specific weight for each domain. We believed using wider scales of 0 to 100 points would allow us to calculate more granular performance scores for IOTA participants and provide greater differentiation between IOTA participants' performance. In the future, we believed this methodology for assessing performance could be applied with minimal adaptation to future IOTA participants if CMS adds other types of organ transplants to the model through rulemaking. We believed that the approach of awarding points in the achievement, efficiency, and quality domains for a score out of 100 points represented the best combination of flexibility and comparability that would allow us to assess participant performance in the IOTA Model.

As discussed in section III.C.5.b of the proposed rule, the proposed performance domains and scoring structure would also allow us to combine more possible metric types within a single framework. We believed that this approach allows for more pathways to success than performance measurement based on relative or absolute quintiles, which were also alternatively considered, as it would reward efforts made towards achievable targets.

As discussed in section III.C.5.b of the proposed rule, we considered more than three domains to assess performance, which would potentially offer IOTA participants more opportunity to succeed due to the ability to maximize points in different combinations of domains. The more domains there are, the more the maximum points possible in each domain are spread out. However, we limited the number of domains to three to ensure the model is focused and goal-oriented, thus promoting, encouraging, and driving improvement activity and care delivery transformation across IOTA participants that evidence suggest may help achieve desired outcomes. Desired outcomes include delaying or avoiding dialysis, improving access to kidney transplantation by reducing barriers and disparities, reducing unnecessary deceased donor discards, increasing living donors, and improving care coordination and quality of care pre and post transplantation. We believed that the three domains and the proposed performance scoring structure would offer IOTA participants multiple paths to succeed in the proposed IOTA Model due to the ability to maximize points in different combinations of domains.

In section III.C.5.b of the proposed rule, we also considered not using the three performance domains and scoring structure, instead opting for alternative methods. We considered a performance assessment methodology in which an IOTA participant's performance on a metric would be divided by an expected value for each metric, which would indicate whether an IOTA participant is performing better or worse on a given measure than expected. We would then calculate a weighted average of all performance scores to reach a final score. However, we believed that setting appropriate targets of expected performance for each IOTA participant for each metric would be unrealistic to implement. The additional methodological complexity necessary for this approach would be difficult for an IOTA participant to incorporate into its operations and data systems, thereby limiting an IOTA participant's ability to understand the care practice changes it would need to make to succeed in the IOTA Model.

As discussed in section III.C.5.b of the proposed rule, we also considered assessing IOTA participant performance solely on magnitude of increased transplants over expected transplants. Under this approach, an IOTA participant's number of transplants furnished in a given PY subtracted from expected transplants would show a numeric net gain or loss in total transplants. This net value would be multiplied by an IOTA participant's kidney transplant survival rate to generate a total score for each IOTA

participant. This option would reward successfully completed transplants. This methodology reflects the goals of the IOTA Model and acknowledges that kidney transplant failures are an undesirable outcome. In addition, the methodology is simple to evaluate and understand, requiring only two inputs and a simple calculation. However, this approach does not account for efficiency and quality domain metrics, as proposed in sections III.C.5.d. and III.C.5.e of the proposed rule, which we believed to be important goals of the model. Thus, we did not propose this method to assess IOTA participant performance.

As discussed in section III.C.5.b of the proposed rule, we also considered directly translating the benefits of a kidney transplant by measuring the net effect of increased transplants and post-transplant care at the IOTA participant level. In a performance scoring methodology focused on the net effect of increased transplants and post-transplant care, the number of kidney transplants performed in a given PY would be compared to a benchmark year for the IOTA participant. Each additional kidney transplant would then be multiplied by the expected number of years of dialysis treatment the transplant averted, based on organ quality. Post-transplant care would analyze observed versus expected kidney transplant failures. For IOTA participants that achieved fewer kidney transplant failures than expected, the difference in volumes would be translated into life-years. Each marginal additional year of averted dialysis care would be used to determine the performance-based payment. Because calculating expected transplant failures is a complicated calculation with assumptions based on organ quality, donor age, and donor health conditions, a scoring system of this type would require us to make multiple broad assumptions about individual transplants or average scores across all transplants performed by the IOTA participant to create an accurate estimate of the total number of years of dialysis treatment the kidney transplant averted. This level of complexity would also introduce operational risks and burden. This approach would be aligned with the goals of the IOTA Model as it relates to increasing the number and access to kidney transplants but would still require CMS to separately assess performance on proposed performance measures for the IOTA Model, as discussed in sections III.C.5.c, III.C.5.d, and III.C.5.e of the proposed rule.

We solicited feedback from the public on our proposal to assess IOTA participant performance in three domains: (1) achievement domain; (2) efficiency domain; and (3) quality domain. We also sought feedback on our proposed performance scoring approach that would weigh the achievement domain higher than the efficiency and quality domain, and our proposed use of a 0 to 100 performance scoring approach to determine if and how performance-based payments would apply. Additionally, we invited feedback on the alternatives considered.

The following is a summary of the comments received on our proposal to assess IOTA participant performance in three domains (achievement domain, efficiency domain and quality domain), our proposed performance scoring approach, and on our proposed use of a 0 to 100 performance scoring approach to determine if and how performance-based payments would apply and our responses:

Comment: A few commenters supported the three proposed domains for assessing an IOTA participant's performance. A commenter specifically stated they supported the 100-point structure made up of 3 domains and another specifically stated their support for the emphasis on the achievement domain.

Response: We thank the commenters for their support.

Comment: A commenter stated that the performance metrics are conflicting because while volume is incentivized, achieving a high organ offer acceptance rate ratio would require more conservative transplants.

Response: We appreciate the commenters feedback. We believe that counterbalanced performance metrics are needed to create checks and balances within the IOTA Model. The inclusion of the organ offer acceptance rate ratio metric and the composite graft survival rate discourages IOTA participants from strictly considering volume and encourages IOTA participants to also prioritize long term outcomes. We direct readers to sections III.C.5.d(1) and III.C.5.e(1) of this final rule for further discussion on the organ offer acceptance rate ratio and the composite graft survival rate. The collection of metrics encourages IOTA participants to understand specific components of their transplant program that may be optimized such as utilizing filters, understanding what organs they are accepting or deferring and identifying what workflows and resources may help them optimize their transplant program. While IOTA participants may believe it is contradictory to weight achievement higher, we believe that kidney transplant volume can be increased while being mindful of post-transplant outcomes for both living donor and deceased donor transplant recipients. There are a variety of ways for IOTA participants to reach final performance point totals that are incentivized (score greater than 60). For example, growth of a living donor program could increase volume without impacting the offer acceptance ratio entirely.

Comment: Many commenters stated that the performance should include other factors that could impact an IOTA participant's performance, such as the IOTA participant's history.

Response: We appreciate the commenters' feedback. We believe that IOTA participant history is incorporated into many features and performance measurements of the IOTA Model. An IOTA participant's past performance is included in the achievement domain of the IOTA Model, by using baseline year data to calculate kidney transplant volume goals in the IOTA Model. While there is not an improvement scoring component within the achievement domain, we intend to consider this for future rulemaking. The organ offer acceptance rate ratio performance metric, which is part of the efficiency domain, is evaluated either through overall achievement or improvement. Inclusion of an improvement scoring system within the efficiency domain, takes the IOTA participant's history into consideration. The quality domain utilizes composite graft survival over a 6-year period as a performance metric. While use of this metric in the first 1–2 years of the model will not take IOTA participant history into consideration, the latter years will include earlier model data years (IOTA participant history) in its calculation.

Comment: Many commenters suggested that risk adjustment should be included in the performance measures, with a couple of commenters stating specifically that the lack of adjustment incentivizes transplanting healthier individuals and avoiding higher risk organs. Another commenter relayed their concern about the lack of scientific validation for the metrics, from the transplant community.

Response: We thank the commenters for submitting their concerns. The data and methodology utilized for the offer acceptance ratio utilizes OPTN data and SRTR methodology and is risk adjusted. As mentioned in section III.C.5.e(1)(a) of this final rule, we considered whether donor demographic characteristic risk adjustments such as race, gender, age, disease condition and geographic location would be significant and clinically appropriate for our approach

in calculating the composite graft survival rate measure, however, we are unsure which specific adjustments would be most appropriate. We believe that further analysis of the impact of the donor's characteristics on graft survival is necessary prior to incorporating a risk adjustment methodology. Additionally, given that the IOTA Model is 6 years, and the measure is rolling, we want to make sure that we continue discussions to ensure that this measure eventually includes a robust and appropriate risk adjustment methodology. We direct readers to section III.C.5.e(1)(a) of this final rule, for further discussion regarding calculation of the composite graft survival rate.

While the achievement domain does not utilize risk adjustment, it assigns points for volume of kidneys transplanted, based on an IOTA participant's prior performance and national growth rate. We did not originally consider how volume goals could be risk adjusted, however, we are open to ongoing feedback as to how this could be integrated into the achievement domain metric.

We acknowledge the concerns raised by a commenter about the scientific validity of some performance measures, but we do not believe any of the measures are entirely novel. For example, the OPTN has previously used an offer acceptance rate ratio in their metrics. Although the proposed composite graft survival rate measure is new, analyzing 1-year graft survival is an established performance metric familiar to kidney transplant hospitals. We will consider risk-adjusting this metric in future rulemaking. The IOTA Model intends to closely monitor metrics new to the transplant community and adjust as indicated throughout its performance years.

Comment: A couple of commenters mentioned that performance assessment should include a measure of additional relevant factors, such as the donor's risk factors.

Response: We agree and note that the SRTR calculation, which is used for the organ offer acceptance rate ratio calculation, includes numerous donor factors that contribute to the acceptance predictors.[192] While the composite graft survival rate metric is not risk adjusted, we will stratify the data from the composite graft survival rate measure and consider public comments to inform a risk adjustment methodology for this measure and intend to address a new or updated policy pursuant to future rulemaking. We direct readers to section III.C.5.e(1) of this final rule for further discussion on the composite graft survival metric.

Comment: Several commenters stated that measures of transplant outcomes should be a reliable and valid measure and that a SRTR metric is an example of a metric that should be used.

Response: We agree and note that the SRTR calculation, which is used for the organ offer acceptance rate ratio calculation, includes numerous donor factors that impact the acceptance predictors.[193] While the composite graft survival rate metric is not risk adjusted, we will stratify the data from the composite graft survival rate measure and consider public comments to inform a risk adjustment methodology for this measure and intend to address a new or updated policy pursuant to future rulemaking. We direct readers to section III.C.5.e(1) of this final rule for further discussion on the composite graft survival metric.

Comment: Several commenters conveyed concern that CMS should exclude hospice patients from the one-year mortality rate.

Response: We appreciate the commenters' concern. The IOTA Model does not currently include a one-year mortality performance measure, and therefore discussion about hospice patient exclusions from this metric is not applicable. For clarification, the IOTA Model does include a composite graft survival rate metric, but this metric is based on graft survival, not patient survival. Any specifications on exclusions for calculating the composite graft survival rate metric would be addressed in detail in future IOTA Model methodology reports.

Comment: Several commenters conveyed concern that assessment scoring places a heavy weight on the volume of transplants and the subsequent possibility that this may incentivize IOTA participants to use ''sub-par'' organs and increase disparities.

Response: We agree that there is a heavy focus on increasing volume of transplants as this is one of the primary goals of the IOTA Model. There are a variety of ways to increase kidney transplant volume (for example, expanding a living donor program, increasing volume of patients active on the kidney transplant list, utilizing filters to ensure appropriate offers for risk thresholds, or using kidney transplants from underutilized categories, if reasonable). While some kidney transplant hospitals may prioritize increasing kidney transplants from underutilized categories such those with a high KDPI or donation after circulatory death (DCD) kidneys, that decision may hinge on resources, and is not a requirement.

The IOTA Model was designed to create balance by requiring that IOTA participants perform well in the efficiency and quality domains to reach positive performance incentives. This ensures that kidney transplant volume does not grow unchecked, and IOTA participants remain responsible for long term outcomes of patients. We believe that increasing kidney transplants will result in increases in patient access to transplant along the continuum of care—ranging from being referred for transplant, to waitlisting, to transplant. Given the disparities that exist in all phases of transplant, we believe that changes made to increase kidney transplant volume will also help reduce disparities. Additionally, we believe the proposed transparency measures, which include publishing the criteria used to select transplant patients and reviewing the acceptance criteria as described and finalized in sections III.C.8.a(1) and (2) of this final rule, complement the performance-based metrics and will help to reduce disparities by increasing patient awareness and encouraging shared decision-making. We direct readers to section III.C.8(a) of this final rule for a full discussion on the transparency requirements. We intend to monitor throughout the entirety of the model for any unintended consequences that would impact disparities.

Comment: Numerous commenters expressed concern regarding the weighting of points for each domain. Several commenters stated that the point allocation for each performance domain should be spread equally across domains or that more points should be allocated to the quality domain (one example specified 50 achievement points, 30 quality points, 20 efficiency points). A commenter suggested that quality should have the highest weight, while another recommended equal weighting of achievement and quality due to resources needed for post-transplant care, which they felt was not reimbursed. A commenter suggested that during PY 3 or later, CMS should consider the point breakdown of 50, 25, 25 for the achievement, efficiency and quality domains. There were many specific concerns that there is too much incentive placed on volume rather than quality and this may incentivize poor long-term outcomes for patients. A commenter was specifically concerned

[192] Scientific Registry of Transplant Recipients. (n.d.). *Risk Adjustment Model: Offer Acceptance.* Offer acceptance. *https://www.srtr.org/tools/offer-acceptance/.*

[193] Ibid.

about the risk of increased performance reviews.

Response: We appreciate the commenters' concerns but respectfully disagree. We believe that the domain with the heaviest weighting, will also be the domain that sees greatest behavioral changes. Therefore, the achievement domain is more heavily weighted to increase access to transplant, a primary goal of the IOTA Model. If an IOTA participant prioritizes growth of their living donor program, for example, this would have a high likelihood of better post-transplant outcomes, given the longer graft lives of living donor kidney transplants. IOTA participants that may be restricted to expanding living donation could consider, for example, how to optimize their organ filters to ensure that they receive more of the transplant offers they are willing to accept and transplants they can help maintain long term. IOTA participants can earn up to 60 points for performance in the achievement domain and up to 40 combined points for performance metrics in the efficiency and quality domains. We do not believe this is imbalanced given the reasoning previously mentioned. Additionally, as described and finalized in section III.C.5.e of this final rule, we are modifying the metrics proposed for inclusion in the quality domain. As such, we do not believe that weighting the quality domain metrics more heavily is appropriate at this time. We direct readers to section III.C.5.e of this final rule for further discussion on the quality domain. We will continue to monitor our performance assessment strategy across all performance domains and may consider proposing an updated performance scoring approach through future rulemaking. We will be finalizing our performance scoring approach in section III.C.5.b of this final rule, as proposed, which designates 3 performance domains and the performance scoring approach as follows: 60 points for the achievement domain, 20 points for the efficiency domain and 20 points for the quality domain.

Comment: A couple of commenters stated their concerns that prioritizing kidney transplant volume in the achievement domain may discourage IOTA participants from taking on more complex cases, because patients may need more assistance throughout transplant evaluation or may be at risk of worse outcomes.

Response: We appreciate the commenters' feedback but believe that kidney transplant hospitals have different skill sets and resources. The IOTA Model encourages IOTA participants to work at the top of their scope and encourages them to identify ways that they can optimize their program without compromising post-transplant care. Approaches may look very different depending on the size, location and resources of an IOTA participant. For example, well-established IOTA participants may focus on improving outcomes for patients receiving kidneys with a KDPI greater than 85, whereas small IOTA participants may decide to focus on pre-emptive transplant or living donation transplant. Risk thresholds may also vary considerably based on the established networks between community nephrologists and transplant teams. Community nephrologists are an extension of the transplant team and can have significant impact on helping their patients successfully receive a transplant and maintain graft life, after transplant. The IOTA Model challenges the pre-existing framework of kidney transplant hospitals to evolve.

While we believe that increasing access to transplant and subsequent increase in volume is a fundamental goal of the IOTA Model, we believe there is also opportunity to encourage and reward IOTA participants that excel in the efficiency and quality domains as they adapt their programs for growth. It is ideal for IOTA participants to excel across all three performance domains throughout the model test; however, we understand that IOTA participants may perform better in specific performance domains due to year-to-year variations in available resources. The IOTA Model scoring was designed to include post-transplant measures to prevent poor outcomes from increased kidney transplant volume.

Comment: A commenter recommended that CMS include nutritional care in their performance metrics to address needs of patients.

Response: While we acknowledge the importance of nutrition and nutritional resources for patients across the CKD to ESRD to transplant care continuum, we do not currently believe that that nutritional care directly aligns with the goals of the IOTA Model or its performance metrics. We invite ongoing input on how nutritional care may fit into an alternative quality metric utilized in future iterations of the IOTA Model.

Comment: A commenter stated that safety net kidney transplant hospitals in remote regions will be disadvantaged by the three domains.

Response: We acknowledge that remote and safety net kidney transplant hospitals have different challenges in their transplant programs than kidney transplant hospitals that may be in highly populated areas. We encourage IOTA participants to consider the numerous approaches that they may take to increase kidney transplant volume. This may be achieved by increasing living donor kidney transplants (LDKTs), deceased donor kidney transplant (DDKTs) or both. If an IOTA participant struggles to increase their volume initially, there are opportunities to excel in the efficiency and quality domains. We understand that any model can have unintended consequences and we intend to monitor the model impacts on IOTA participants.

Comment: A couple of commenters suggested that the IOTA Model should have been weighted to encourage use of kidneys with a KDPI greater than 85 and improving quality of care for those transplant recipients, rather than prioritize increasing total number of transplants performed.

Response: Thank you for submitting feedback, however, we disagree. While there is opportunity to optimize use of kidneys with a KDPI greater than 85, we believe this may not be the most ideal way for all IOTA participants to increase volume or general performance. Prioritizing an increase in any DDKTs or LDKTs of a specific classification allows each IOTA participant to have flexibility in adapting their program to meet this goal.

While the IOTA Model is not finalizing a performance metric measuring utilization of kidneys with a KDPI greater than 85, we intend to assess and monitor the utilization of this category of kidney transplants by IOTA participants.

Comment: A commenter was concerned that the IOTA Model does not account for recovered kidneys that are not used for transplant or for non-utilization.

Response: We thank the commenter for their feedback. The organ offer acceptance rate ratio is calculated by excluding donor kidneys that are not utilized. While no metric in the IOTA Model specifically looks at the total non-utilization number, this may be an important metric to further research as it may be impacted differently as kidney transplant hospitals adjust their offer acceptance filters. We believe there may be opportunity for future collaboration with the OPTN to ensure non-utilization data is captured and accessible for review.

Comment: A commenter mentioned concern that CMS is basing kidney transplant hospital percentile rankings against both participating and non-

participating kidney transplant hospitals.

Response: We thank the commenter for submitting their concern. IOTA participants are awarded points in the achievement domain based on performance improvement relative to historical performance for volume of kidneys transplanted. We direct readers to section III.C.5.c of this final rule for a full discussion of the achievement domain.

As described and finalized in section III.C.5.d.(1).(b). of this final rule, the efficiency domain applies a two-scoring system (achievement score and improvement score) based on its performance on the OPTN organ offer acceptance rate ratio; awarding points equal to the higher of the two scores to the IOTA participant. For achievement scoring in the quality domain, as described and finalized in section III.C.5.d.(1).(b). of this final rule, points earned will be based on the IOTA participants' performance on the organ offer acceptance rate ratio relative to national ranking, including all eligible kidney transplant hospitals (both those selected and not selected as IOTA participants), and awarded based on national quintiles. For improvement scoring in the efficiency domain, as described and finalized in section III.C.5.d.(1).(b). of this final rule, points earned will be based on the IOTA participants' performance on organ offer acceptance rate ratio during a PY relative to their performance during the third baseline year for the PY that is being measured. We direct readers to section III.C.5.d of this final rule for a full discussion on the efficiency domain.

Lastly, as described and finalized in section III.C.5.e(1)(b) of this final rule, IOTA participants will earn points in the quality domain based on its performance on the composite graft survival rate, as described and finalized in section III.C.5.e(1)(a) of this final rule, ranked nationally, inclusive of all eligible kidney transplant hospitals. IOTA participants will be awarded points on the composite graft survival rate based on the national quintiles, as outlined in Table 1 to Paragraph (d) at § 512.428. We direct readers to section III.C.5.e of this final rule for a full discussion on the quality domain.

The IOTA Model incentivizes high performance through a point-based system, which we anticipate will drive IOTA participants to outperform non-participating kidney transplant hospitals, which we view as a notable strength of the model.

Comment: A commenter stated the IOTA Model methodology does not account for kidney transplant hospitals that already perform a high-volume of kidney transplants, and instead is based solely on improvement.

Response: We thank the commenter for expressing their concern. Many high-volume kidney transplant hospitals have a combination of well-developed living donor programs, resources such as perfusion pumps, and the volume that allows higher risk thresholds both for accepting certain donors and accepting candidates with more co-morbidities. These qualities and resources allow ongoing opportunity for growth. We recognize that IOTA participants with varying kidney transplant volumes will have unique challenges. However, we believe the methodology's built-in flexibility enables IOTA participants to adapt their kidney transplant hospital to best serve their patient populations. We intend to closely monitor kidney transplant volume growth and outcomes for IOTA participants of all kidney transplant volume sizes and take this into consideration in future rulemaking.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed provisions to assess IOTA participants in the achievement domain, efficiency domain and quality domain and performance scoring approach at § 512.422(a), without modification. We are also codifying the proposed definition of final performance score at § 512.402, without modification. We direct readers to sections III.C.5.c, III.C.5.d, and III.C.5.e of this final rule for further discussion on our proposed achievement domain, efficiency domain, and quality domain. We also direct commenters to section III.C.6.c of this final rule for further discussion on our proposed performance-based payment methodology.

c. Achievement Domain

In section III.C.5.b of the proposed rule, we proposed measuring IOTA participant performance across three domains, one of which is the achievement domain. We proposed to define ''achievement domain'' as the performance assessment category in which CMS assesses the IOTA participant's performance based on the number of transplants performed on patients 18 years of age or older, relative to a target, subject to a health equity performance adjustment, as described in section III.C.5.c.(3) of this final rule, during a PY. We proposed to use OPTN data, regardless of payer, and Medicare claims data to calculate the number of kidney transplants performed during a PY by an IOTA participant on patients 18 years of age or older at the time of transplant, as described in section III.C.5.c(2) of this final rule.

In section III.C.5.c of the proposed rule, we proposed to set the participant-specific target for the achievement domain based on each IOTA participant's historic number of transplants. A central goal of the proposed IOTA Model test is to increase the number of kidney transplants furnished by IOTA participants, which we believed would be possible via care delivery transformation and improvement activities, including donor acceptance process improvements to reduce underutilization and discards of donor kidneys. We believed IOTA participants may also increase the number of kidney transplants furnished to patients by improving or implementing greater education and support for living donors.

As discussed in section III.C.5.c of the proposed rule, we considered constructing and using a transplant waitlisting rate measure or using SRTR's transplant rate [194] rather than measuring number of transplants performed relative to a participant-specific target for the achievement domain. Research has suggested that including such a metric could demonstrate the need for both living and deceased donor organs for a particular transplant hospital and be less reliant on organ availability for a particular geographical area.[195] Research also suggested that the inclusion of a pretransplant measure, such as waitlisting rate, may allow for a more complete assessment of transplant hospital performance and provide essential information for patient decision-making.[196] However, for the IOTA Model, we proposed to test the effectiveness of the model's incentives to change outcomes, rather than on processes. The relevant outcome for purposes of the IOTA Model is the receipt of a kidney transplant, not

[194] For additional information on SRTR's transplant rate measure, please see *https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports#figurea2.*

[195] Paul, S., Melanson, T., Mohan, S., Ross-Driscoll, K., McPherson, L., Lynch, R., Lo, D., Pastan, S.O., & Patzer, R.E. (2021). Kidney transplant program waitlisting rate as a metric to assess transplant access. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 21*(1), 314–321. *https://doi.org/10.1111/ajt.16277.*

[196] Paul, S., Melanson, T., Mohan, S., Ross-Driscoll, K., McPherson, L., Lynch, R., Lo, D., Pastan, S.O., & Patzer, R.E. (2021). Kidney transplant program waitlisting rate as a metric to assess transplant access. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 21*(1), 314–321. *https://doi.org/10.1111/ajt.16277.*

getting on and remaining on the kidney transplant waitlist. Additionally, the SRTR transplant rate measure calculates the number of those transplanted as a share of the kidney transplant hospital's waitlist, which we believed does not reflect the variety of ways that kidney transplant hospitals construct their waitlist practices. For example, for some kidney transplant hospitals, the number of kidneys transplanted as a share of their ''active'' waitlist transplant candidates may be a more accurate representation of their waitlist practices. Thus, we did not believe this was appropriate to propose for the IOTA Model.

We sought comment on our proposed achievement domain performance metric and alternative methodologies considered for assessing transplant rates.

The following is a summary of the comments received on our proposed achievement domain performance metric and alternative methodologies considered for assessing transplant rates and our responses:

Comment: A couple of commenters supported the achievement domain performance metric. A commenter specifically agreed with not including a waitlisting measure.

Response: We thank the commenters for their support of the achievement domain.

Comment: Several commenters stated their concern that there is a heavy weight placed on the volume of transplants and that this may incentivize participants to use ''sub-par'' organs and increase disparities.

Response: We agree that there is a heavy focus on increasing volume of transplants as this is one of the primary goals of the IOTA Model. There are a variety of methods that IOTA participants may choose to increase kidney transplant volume including, but not limited to, expanding a living donor program, increasing volume of patients active on the kidney transplant list, utilizing filters to ensure appropriate offers for risk thresholds, or using kidney transplants from underutilized categories. While some kidney transplant hospitals may prioritize increasing kidney transplants from underutilized categories such those kidneys with a KDPI greater than 85 or DCD kidneys, that decision may hinge on resources, and is not a requirement. We are unsure if the commenters are defining ''sub-par'' organs as organs that should not be offered to any candidates or as organs that are only acceptable in specific scenarios. We believe it will be important for IOTA participants to further consider what is a ''sub-par'' kidney. While certain kidneys may not be ideal for some waitlist candidates, they may be a potential opportunity in another scenario.

Comment: Commenters voiced concerns about how the achievement domain would impact high performing IOTA participants. Some commenters worried the proposed scoring system would penalize IOTA participants who have historically been top performers. Another commenter suggested CMS credit the top 20 percent of IOTA participants to maintain their kidney transplant volume, while using different incentives for lower-performing IOTA participants.

Additionally, a commenter expressed concern that increasing kidney transplant volume often involves transplanting more high-risk organs. While SRTR accounts for how this impacts outcomes, the commenter argued that it does not consider the added strain on resources at high performing kidney transplant hospitals. Lastly, another commenter worried the achievement domain would penalize IOTA participants who are already operating at full kidney transplant capacity, unless they made substantial new investments.

Response: We appreciate the concerns that the commenters have submitted, and we acknowledge the efforts exerted by transplant hospitals to reach their status. We believe that IOTA participants can potentially become ''high performing'' through a variety of practices such as utilizing kidneys of all KDPI scores when appropriate, adjusting filters, or expanding their living donor program. We believe that with the number of ways that an IOTA participant can become more efficient and have higher kidney transplant volumes, that they have additional opportunities to improve their performance and to continue increasing kidney transplants. We believe that the updated methodology for setting transplant targets, as described and finalized in section III.C.5.c(1) of this final rule, and the updated scoring methodology in the achievement domain, as described and finalized in section III.C.5.c(2) of this final rule, will make it more achievable for IOTA participants of all sizes to achieve maximum points in the achievement domain. We direct readers to section III.C.5.c(1) and III.C.5.c(2) of this final rule for a full discussing on the updated methodology for calculating the transplant target and the updated scoring methodology in the achievement domain. We also note that, as described and finalized in section III.C.6.c(2) of this final rule, there is no downside risk payment in PY 1 of the IOTA Model.

Comment: A couple of commenters stated that CMS should act to eliminate constraints on transplant availability due to both kidney transplant hospital and hospital capacity and organ availability before implementing transplant targets in the achievement domain.

Response: We appreciate the commenters' feedback; however, we do not have control over the capacity of kidney transplant hospitals and hospitals or organ availability. We encourage kidney transplant hospitals to work with their leadership if they have concerns about capacity limitations. Organ availability is impacted by a variety of factors, including, but not limited to identification of organ donors, allocation practices, location of kidney transplant hospitals and donors and utilized organs. Improving kidney transplant volumes will require multi-pronged efforts. We believe the IOTA Model will help increase the number of kidney transplants performed.

Comment: A few commenters suggested that CMS should engage with stakeholders to refine goals and focus more narrowly on certain aspects of increasing transplant volume in the achievement domain, especially increasing living donation and utilizing high-risk kidneys. Similarly, a commenter suggested that CMS should focus its efforts on increasing kidney volume in categories where there is opportunity for growth such as high KDPI kidneys, donor kidneys with acute kidney injury (AKI) and DCD kidneys.

Response: We thank the commenters for their suggestions and believe that there are a variety of practices that IOTA participants can choose to utilize when increasing their kidney transplant volume. Because kidney transplant hospitals vary significantly, we disagree with the commenters, and do not believe it would be appropriate to be prescriptive about how an IOTA participant decides to increase their kidney transplant volume. While living donation, for example, has had relatively unchanged transplant rates over the last few years, indicating opportunity for improvement, we acknowledge that not every kidney transplant hospital has the same resources or characteristics.[197] Furthermore, we believe the IOTA Model design provides flexibility that enables IOTA participants to increase

[197] United States Renal Data System. 2022. USRDS Annual Data Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 7: Transplantation. Figure 7.10b.

their kidney transplant volume in a way that best suits their transplant program and community.

Comment: A couple of commenters voiced concern that success in the achievement domain is contingent upon a multitude of uncontrollable factors, such as limited organs and matching challenges. Additionally, a few commenters mentioned concern that increasing kidney transplant volume requires expansion of many other resources for successful post-transplant care, which are not reimbursed through the Medicare cost report.

Response: We appreciate the commenters' feedback about their concern about limitations of resources. We acknowledge the multitude of factors that can impact kidney transplant hospital volume—from a community level to a nationwide level, and also acknowledge that kidney transplant volume expansion may require increased resources, particularly staffing. There are intrinsic components of the IOTA Model intended to offset challenges of the achievement domain, such as two other performance domains (efficiency and quality). Additionally, the achievement domain calculates transplant targets for IOTA participants based on an IOTA participant's own prior kidney transplant volume in their baseline years and based on a national growth rate that accounts for changes year to year (as described in section III.C.5.c.2 of this final rule). We also note that there are not prescriptive specifications in the achievement domain requiring IOTA participants to meet transplant volumes in one specific way. This flexibility allows IOTA participants to identify what method is best to optimize their kidney transplant volume. Notably, as described and finalized in section III.C.6.c(1) of this final rule, PY 1 does not include any downside risk payments regardless of an IOTA participant's final performance score. Furthermore, we believe the neutral zone has a reasonable final performance score range for PYs 2–6, as described and finalized in section III.C.6.c(1) of this final rule. As such, we believe the absence of downside risk payment in of PY 1 creates a buffer for IOTA participants to anticipate resources needed to succeed in PY 2.

The achievement domain scoring methodology accounts for Medicare and non-Medicare patients who receive a kidney transplant. We anticipate that since IOTA participants will aim to increase kidney transplants for all kidney transplant waitlist patients, this will create opportunities to accumulate payment through the IOTA Model incentives and through payment by both Medicare and private payers for kidney transplant related services. We believe these payments should assist in costs that IOTA participants may encounter while participating in the IOTA Model.

Comment: A commenter conveyed concern that the achievement domain, which focuses on increasing kidney transplant volume, is contradictory since the Innovation Center's goals have traditionally been to improve value versus volume. A few commenters were concerned that volume does not equate with better outcomes and even with counterbalances in the model, will pressure IOTA participants to complete riskier transplants, which may have worse outcomes.

Response: We disagree and believe that the achievement domain simultaneously supports increasing kidney transplant volume and value. There are almost 5,000 patients who die annually while being on the kidney transplant waitlist.[198] It is well known the life span of and lifestyle of those patients on dialysis is drastically different from those patients who receive kidney transplants. Not only does the model aim to improve access, kidney transplant volumes and quality of life, but also reduce spending. The cost of yearly dialysis far exceeds the average cost of immunosuppression and post-transplant care. The IOTA Model is not encouraging IOTA participants to transplant non-viable organs or organs where risks outweigh the benefits. The IOTA Model design, does however, challenge kidney transplant hospitals to optimize all components of care from waitlisting to transplant to post-transplant. Growth in living donor programs is a prime example of how increasing volume should not compromise outcomes and should improve overall outcomes. As for increases in DDKT volume, we plan to carefully monitor volume, organ offer acceptance ratios and composite graft survival independently and collectively to monitor for unintended consequences and will consider this for future rulemaking for PY 2. We encourage commenters to provide feedback in the future about (1) what they define as ''riskier'' transplants from the perspective of the donor and recipient (2) whether this is specific to KDPI values or qualities of the donor kidney and (3) if this exceeds the risk of being on dialysis.

Comment: A few commenters believe that the achievement domain disadvantages smaller transplant programs due to their lack of COE designation and overlooks challenges to gain this designation. Another commenter was concerned that small transplant programs will have to accept higher risk kidneys. A commenter suggested that smaller programs should have separate performance metrics.

Response: We thank the commenters for their feedback and acknowledge that kidney transplant hospitals of different sizes, will have different challenges in increasing kidney transplant volume. Kidney transplant hospitals that fall below the low volume threshold would be excluded from the IOTA Model, as described and finalized in section III.C.3(c) of this final rule. Based on the updated scoring methodology in the achievement domain, as described and finalized in section III.C.5.c(2) of this final rule, an IOTA participant with 20 kidney transplants during the baseline years (with an example growth rate of 8 percent) would need a total of 27 kidney transplants to earn maximum achievement points (60), or approximately 23 kidney transplants to earn 40 points in the achievement domain. We believe that offering wide neutral margins for final performance scores and offering a variety of opportunities to gain points in the achievement domain, efficiency domain and quality domain creates balances for a different size kidney transplant hospital. We believe that increasing kidney transplant volume will create opportunities for smaller kidney transplant hospitals to qualify for COE designation in the future.

Comment: A couple of commenters raised concerns that the achievement domain disproportionately impacts large transplant programs due to the demand on resources it would require and the general volume requirements.

Response: We thank the commenters for submitting their concerns. As stated in response to small kidney transplant hospital concerns, offering wide neutral margins for final performance scores and offering a variety of opportunities to gain points in the achievement, efficiency and quality domains creates balances for IOTA participants. Many large kidney transplant hospitals have significant resources, COE designation, and paired donation opportunities that may not be available to smaller kidney transplant hospitals. We believe that while volume goals may be higher, they are proportionately similar for kidney transplant hospitals of different sizes.

[198] Penn Medicine News. (2020, December 16). *Too Many Donor Kidneys Are Discarded in U.S. Before Transplantation—Penn Medicine. www.pennmedicine.org. https://www.pennmedicine.org/news/news-releases/2020/december/too-many-donor-kidneys-are-discarded-in-us-before-transplantation.*

Comment: A commenter suggested that IOTA participant specific volume targets should match local population needs along economic lines, racial lines and payer sources to increase equitable access to underserved groups.

Response: We thank the commenter for their feedback. While this is not a specific requirement that we originally proposed, we are interested to receive more information about this suggestion, as we consider future rulemaking. First, we would want to consider how to do this equitably and how kidney transplant hospitals would identify their local population needs.

Comment: A commenter suggested that CMS track achievement domain volume scores to ensure IOTA participants do not utilize the scoring system at the expense of patient risk.

Response: We appreciate the commenter's response. The IOTA Model has thoughtfully been designed to create counterbalances between measures. For example, although the achievement score is based on kidney transplant volume, the efficiency score is based on offer to acceptance ratios and the quality domain includes a composite graft calculation for a 6-year period post-transplant. While innovation models are not perfect, and are corrected for optimization over time, we believe that IOTA participants that have combined accountability for IOTA Model requirements, OPTN metrics and regulatory and ethical requirements, will be mindful of avoiding inappropriate patient risk.

Comment: A commenter recommended that CMS differentiate between more established kidney transplant hospitals and newer kidney transplant hospitals with shorter track records and transplant volume. Established kidney transplant hospitals often have decades-long waitlists, referral networks, and stable staffing of transplant nephrologists. In contrast, newer, smaller kidney transplant hospitals can experience large swings in transplant volume due to growing pains. Furthermore, the commenter argued, the loss of a single transplant nephrologist can halt kidney transplants at these newer kidney transplant hospitals while they recruit replacements, leading to a penalty at a time when the kidney transplant hospital can least afford it.

Response: We thank the commenter for their feedback. We acknowledge that there are differences between well-established and, newer, smaller kidney transplant hospitals with smaller transplant volume. As described in section III.C.5.c(1) of this final rule, the updated methodology for measuring performance in the achievement domain will be based on the average number of kidney transplants performed in the baseline years trended forward by the national growth rate. Therefore, we disagree with the commenter and believe all IOTA participants can improve their kidney transplant rates, regardless of size. We recognize that some IOTA participants may have to make upfront investments, but the low volume threshold of 11 adult kidney transplants for each kidney transplant hospital in every baseline year, as described and finalized in section III.C.3.c of this final rule, will substantially mitigate the demands placed on, newer, smaller kidney transplant hospitals.

After consideration of the public comments, for the reasons set forth in this rule, we are finalizing, as proposed, our provisions for setting an IOTA participant's transplant target based on each IOTA participant's historic number of transplants at § 512.424(b)(1), as described and finalized in section III.C.5.c(1) of this final rule. We direct readers to section III.C.5.c(1) of this final rule for further discussion on the transplant target methodology. As described and finalized in section III.C.5.c(2) of this final rule, we are also finalizing our proposed provision for identifying kidney transplants performed by an IOTA participant using OPTN data, regardless of payer, and Medicare claims data at § 512.424(d), without modification.

Furthermore, after consideration of the public comments we received, we will not be finalizing a health equity performance adjustment provision, as described in section III.C.5.c(3) of this final rule. Therefore, we are modifying regulatory text for the achievement domain definition at § 512.402, to remove references to a health equity performance adjustment and make minor technical corrections in punctuation. We direct readers to section III.C.5.c(3) of this final rule for further discussion on our proposed health equity performance adjustment. While we are finalizing our provision for setting IOTA participants' transplant target based on each IOTA participant's historic number of transplants as mentioned in section III.C.5.c, we note that the methodology for utilizing an IOTA participant's historic number of transplants for calculating transplant targets has changed in section § 512.424(b)(1) and is described in detail and finalized in section III.C.5.c(1) of this final rule. We direct readers to section III.C.5.c(1) of this final rule for further discussion on the transplant target methodology. In addition, as described and finalized in section III.C.5.c(2) of this final rule, we are finalizing our proposed provision for identifying kidney transplants performed by the IOTA participant using OPTN data, regardless of payer, and Medicare claims data at § 512.424(d), without modification.

(1) Calculation of Transplant Target

In the proposed rule, we proposed that for each model PY, CMS would calculate a ''transplant target'' for each IOTA participant, which would determine performance in the achievement domain. For the purposes of the model, we proposed to define ''transplant target'' as the target number of transplants set for each IOTA participant to measure performance in the achievement domain as described in the proposed rule and section III.C.5.c of this final rule. We proposed that CMS would notify each IOTA participant of their transplant target by the first day of each PY, in a form and manner determined by CMS.

For each PY, we proposed in section III.C.5.c(1) of the proposed rule, that CMS would calculate the transplant target for the achievement domain by first determining the highest number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older in a single year during the baseline years, as defined and finalized in section III.C.3.c. of this final rule. CMS would then sum the highest number of deceased donor kidney transplants and living donor kidney transplants furnished in a single year during the baseline years calculate the transplant target for an IOTA participant, even if those transplant numbers were achieved during different baseline years. We believed that choosing the highest transplant numbers during the baseline years would illustrate the capabilities and capacities of the IOTA participant, and, when combined, would be an appropriate target for number of transplants performed during the PY. We also understood that living donation and deceased donor donation involve different processes by the IOTA participant, so we chose each of those numbers separately to recognize the potential capacity for each IOTA participant for both living and deceased donor transplantation.

In section III.C.5.c(1) of the proposed rule, we proposed that the sum of the highest number of deceased donor and living donor transplants across the baseline years of the IOTA participant would then be projected forward by the national growth rate, as described in section III.C.5.c(1) of this final rule, or

zero should the national growth rate be negative, resulting in the transplant target for a given PY. We proposed to define ''national growth rate'' as the percentage increase or decrease in the number of kidney transplants performed over a twelve-month period by all kidney transplant hospitals except for pediatric kidney transplant hospitals and kidney transplant hospitals that fall below the low volume threshold described and finalized in section III.C.3. of this final rule. We proposed to define ''pediatric kidney transplant hospitals'' as a kidney transplant hospital that performs 50 percent or more of its transplants in a 12-month period on patients under the age of 18. We also proposed that the low volume threshold to be 11 kidney transplants performed for the purposes of calculating the national growth rate. We also proposed this approach for calculating the national growth rate to account for and reflect the growth in organ procurement by OPOs that has occurred, indicating potential growth in the number of available organs.

In section III.C.5.c(1) of the proposed rule, we proposed that CMS would calculate the national growth rate by determining the percent increase or decrease of all kidney transplants furnished to patients 18 years of age or older from two years prior to the PY to one year prior to the PY. Because the proposed national growth rate includes IOTA participants and non-IOTA participant kidney transplant hospitals, we acknowledge that it could make achieving the transplant target number harder. This is why, if the national growth rate becomes negative for a PY, we proposed treating it as zero and CMS would not apply the national growth rate to project forward the sum of the highest number of deceased and living donor kidney transplants furnished in a single year during the baseline years. In other words, an IOTA participant's transplant target would equal the sum of its own highest deceased and living donor transplants furnished across the baseline years if the national growth rate were to be negative for a PY. We also want to be able to share model performance targets with IOTA participants before the start of each PY and are prioritizing ensuring prospectivity over ensuring the most up-to-date trend figures. We also proposed that if the model begins on an any date after January 1, 2025, the trend would also be adjusted.

For example, as described in section III.C.5.c(1) of the proposed rule, to calculate the national growth rate for PY 1 using the proposed model start date of January 1, 2025, CMS would first subtract the total number of kidney transplants furnished to patients 18 years of age or older in 2022 from the total number of kidney transplants furnished to patients 18 years of age or older in 2023. Next, CMS would then divide that number by the total number of kidney transplants furnished to patients 18 years of age or older in 2022 to determine national growth rate. To create the transplant target for each IOTA participant for PY 1 CMS would do the following:

- If the national growth rate is positive, CMS would trend the national growth rate forward for an IOTA participant by multiplying the national growth rate by the sum of the highest number of deceased donor and living donor transplants furnished to patients 18 years of age or older across the baseline years for the IOTA participant.
- CMS would take the product of step 1 and add it to the sum of the highest living donor and deceased donor kidney transplants furnished to patients 18 years of age or old across the baseline years for an IOTA participant.
- The sum of step 2 would be the transplant target for an IOTA participant. However, if the national growth rate were negative, CMS would not trend the growth rate forward for PY 1 and the transplant target would be the sum of the highest living donor and deceased donor kidney transplants across the baseline years.

In section III.C.5.c(1) of the proposed rule, we proposed that when calculating the national growth rate for each PY, CMS would look to the relevant baseline years for that PY, as depicted in Table 1. This approach would mitigate our concern that a static baseline may reward a one-time investment, rather than continuous improvement. The model PYs, as proposed in the proposed rule, would not factor into an IOTA participant's transplant target calculation until PY 3 of the model (January 1, 2027, to December 31, 2027) and the baseline years would not be based exclusively on PYs until PY 5 of the model (January 1, 2029, to December 31, 2029), which may represent an effective phase-in approach to drive improved performance and savings for the Medicare trust fund. We believe that using baseline years to calculate the transplant targets would also account for kidney transplant hospitals that experience changes in strategy or staffing that may affect their capacity to perform transplants at the level that they did in previous years.

TABLE 1: EXAMPLE – PROPOSED BASELINE YEARS FOR CALCULATION OF TRANSPLANT TARGET (FOR PROPOSED MODEL START DATE)

Performance Year	Calendar Year	Highest Number of Living + Highest Number of Deceased from Baseline Years	Trended by National Growth Rate from
1	Jan 1, 2025 — December 31, 2025	CY 2021: January 1, 2021 – December 31, 2021 CY 2022: January 1, 2022 – December 31, 2022 CY 2023: January 1, 2023 – December 31, 2023	CY 2023/CY 2022
2	Jan 1, 2026 — December 31, 2026	CY 2022: January 1, 2022 – December 31, 2022 CY 2023: January 1, 2023 – December 31, 2023 CY 2024: January 1, 2024 – December 31, 2024	CY 2024/CY 2023
3	Jan 1, 2027 — December 31, 2027	CY 2023: January 1, 2023 – December 31, 2023 CY 2024: January 1, 2024 – December 31, 2024 CY 2025: January 1, 2025 — December 31, 2025	CY 2025/ CY 2024
4	Jan 1, 2028 — December 31, 2028	CY 2024: January 1, 2024 – December 31, 2024 CY 2025: January 1, 2025 – December 31, 2025 CY 2026: January 1, 2026 – December 31, 2026	CY 2026/ CY 2025
5	Jan 1, 2029 — December 31, 2029	CY 2025: January 1, 2025 – December 31, 2025 CY 2026: January 1, 2026 – December 31, 2026 CY 2027: January 1, 2027 – December 31, 2027	CY 2027/ CY 2026
6	Jan 1, 2030 — December 31, 2030	CY 2026: January 1, 2026 – December 31, 2026 CY 2027: January 1, 2027 – December 31, 2027 CY 2028: January 1, 2028 – December 31, 2028	CY 2028/ CY 2027

Should we finalize a model start date other than January 1, 2025, we proposed in section III.C.5.c(1) of the proposed rule that the baseline years, as defined and finalized in section III.B.2.c of this final rule, would shift accordingly, as illustrated in Table 2.

TABLE 2: EXAMPLE - PROPOSED BASELINE YEARS FOR CALCULATION OF TRANSPLANT TARGET, FOR POTENTIAL ALTERNATIVE MODEL START DATE

Performance Year	Alternative Year	Highest Number of Living + Highest Number of Deceased from Baseline Years	Trended by National Growth Rate from
1	July 1, 2025 — June 30, 2026	July 1, 2021 – June 30, 2022 July 1, 2022 – June 30, 2023 July 1, 2023 – June 30, 2024	July 1, 2023 – June 30, 2024 / July 1, 2022 – June 30, 2023
2	July 1, 2026 — June 30, 2027	July 1, 2022 – June 30, 2023 July 1, 2023 – June 30, 2024 July 1, 2024 – June 30, 2025	July 1, 2024 – June 30, 2025 / July 1, 2023 – June 30, 2024
3	July 1, 2027 — June 30, 2028	July 1, 2023 – June 30, 2024 July 1, 2024 – June 30, 2025 July 1, 2025 – June 30, 2026	July 1, 2025 – June 30, 2026 / July 1, 2024 – June 30, 2025
4	July 1, 2028 — June 30, 2029	July 1, 2024 – June 30, 2025 July 1, 2025 – June 30, 2026 July 1, 2026 – June 30, 2027	July 1, 2026 – June 30, 2027 / July 1, 2025 – June 30, 2026
5	July 1, 2029 — June 30, 2030	July 1, 2025 – June 30, 2026 July 1, 2026 – June 30, 2027 July 1, 2027 – June 30, 2028	July 1, 2027 – June 30, 2028 / July 1, 2026 – June 30, 2027
6	July 1, 2030 — June 30, 2031	July 1, 2026 – June 30, 2027 July 1, 2027 – June 30, 2028 July 1, 2028 – June 30, 2029	July 1, 2028 – June 30, 2029 / July 1, 2027 – June 30, 2028

We stated in section III.C.5.c(1) of the proposed rule that we believe that IOTA participants could improve on this metric in several ways. For example, IOTA participants could increase the number of kidney organ offers they accept, which would also potentially lead to greater efficiency domain scores. IOTA participants could also invest in a living donation program or modify their OR schedules to facilitate fewer discards due to physician scheduling.

We considered basing the transplant target on the total number of all organ transplants performed by the IOTA participant over the baseline years (89 FR 43518). However, we did not believe this was appropriate because the total would not reflect the specific capabilities of the IOTA participant's kidney transplant program. We also considered adjusting the transplant target by IOTA participant revenue from hospital cost reports. In this scenario, our consideration was to look at historical kidney transplant data as the best predictor, since this reveals the demonstrated capacity for each IOTA participant to complete kidney transplants.

We also considered setting each IOTA participant's transplant target by determining the IOTA participant's average total kidney transplant volume from the three previous years instead of using the sum of the highest living and deceased donor kidney transplant volumes during the baseline years (89 FR 43518). We believe that this methodology would be simpler and result in a transplant target that is potentially more attainable for IOTA participants, assuming that the average kidney transplant volume is lower than the sum of the highest volumes of deceased and living donor kidney transplants. However, we do not believe that this would reflect the potential highest capacity for transplant that we would otherwise like the target to reflect.

We alternatively considered a static or fixed baseline approach for purposes of determining the transplant target for each IOTA participant, as it would minimize operational burden for CMS due to less frequent updates to the transplant target and ensure that the model does not set a moving target year-over-year (89 FR 43518). However, we believe that a fixed baseline may reward a one-time investment, rather than continuous improvement, and may not

account for kidney transplant hospitals that experience changes in strategy or staffing that may affect their capacity to perform transplants at the level that they did in historical years. The rolling baseline approach we proposed uses historical kidney transplant volumes pre-dating the model start date through the first two model PYs, ensuring a phased-in approach before any improvements made during the model performance period are accounted for in the baseline.

We also considered setting the transplant target for IOTA participants based on two baseline years, rather than the proposed methodology of three (89 FR 43518). For the proposed model start date of January 1, 2025, this approach would look at the highest living and deceased volumes from 2022 and 2023, trended by the national growth rate from 2024, to set the transplant target for PY 1. We believe this methodology would be more reflective of recent transplantation volume and account for the changes to the kidney allocation system that were implemented in 2021. However, we believe that using two baseline years to set a transplant target would be more susceptible to temporary market disruptions or fluctuations that may impact IOTA participants capability or capacity to furnish kidney transplants, such as: if the transplant hospital experiences a shortage in transplant surgeons or other critical staff; if the transplant hospital is acquired; or, the occurrence of a natural disaster, pandemic, or other public health emergency or other extreme and uncontrollable circumstance that would require the transplant hospital to temporarily suspend operations. Any of these disruptions or fluctuations could result in an inaccurate transplant target that would not accurately reflect an IOTA participant's volume capability.

We considered determining the national growth rate by calculating separately; (1) the growth rate of the deceased donor target number by the growth in organs procured, and (2) the living donor target number by the national growth rate in living donor transplants (89 FR 43518). However, procurement rates vary nationally depending on variables unique to each geography and local OPO policies.[199] Because we want the model to inspire kidney transplant hospitals to expand living donor programs, not just match national growth rates, we did not believe this alternative methodology was appropriate to propose.

We also considered determining the national growth rate using the following information: (1) the total growth rate in kidney transplants; (2) the change in rate of organs procured by OPOs; (3) the growth rate in kidney transplants in the non-selected portions of the country; and (4) calculating the average growth rate across multiple baseline years (89 FR 43518). However, we believe that the national growth rate in kidney transplants makes the most sense to use as the basis for the model's growth factor because it best reflects volume trends in the kidney transplant ecosystem overall, as it considers all kidney transplant hospitals, not just IOTA participants.

Finally, we also considered a performance assessment methodology for IOTA participants already achieving higher rates of kidney transplantation by assessing each such IOTA participant's total transplant volume as compared to all IOTA participants, rather than on an IOTA participant specific transplant target (89 FR 43518). We believe this methodology is both easy to understand and simple to administer because it rewards IOTA participants for the total number of transplants performed. However, we thought that this methodology would not be fair to IOTA participants that are smaller in size or achieving lower rates of kidney transplantation.

We solicited comment on our proposal to set unique transplant targets for each IOTA participant, the methodology for setting transplant targets, and any alternatives considered.

The following is a summary of the comments received on our proposal to set unique transplant targets for each IOTA participant, the methodology for setting transplant targets, any alternatives considered and our responses:

Comment: Commenters expressed concern over the proposed methodology for calculating unique transplant targets each PY for each IOTA. Many commenters expressed concern that the proposed methodology is impractical as it overestimates a transplant programs capability to increase transplantation throughput unilaterally, such as without significant improvements in organ procurement and distribution by the OPTN and OPOs, factors beyond hospitals' control, does not take into consideration year over year variability in overall donor volume, and could not be achieved without potentially compromising the quality of care and patient safety. Many commenters stated that the proposed transplant target methodology was unsustainable throughout the model, as increasing kidney transplant volume would make it increasingly difficult for IOTA participants to meet ever-higher targets in subsequent PYs, potentially leading to penalties.

Many commenters believed that the proposed methodology for calculating the transplant target for each IOTA participant would be unattainable for high performing transplant hospitals. For example, while a commenter supported comparing a kidney transplant hospital's transplant rates to the national average, they believed that they would be held to an impractically high expectation for growth. The commenter also argued that kidney transplant hospitals already performing in the top 20 percent should not be penalized for failing to reach an unrealistically high transplant rate. Another commenter suggested that they would need to increase their annual adult transplant numbers by 75 to 150 each year. They felt that the ability to achieve this increase would rely on the availability of a sufficient number of viable organs and a significantly increased waitlist. Consequently, they believed that their kidney transplant hospital could potentially achieve that goal and clear their waiting list in the first year; however, this assumption relied on the premise that every patient could be successfully transplanted with an appropriate donor match, which they considered highly unlikely. A commenter believed that the proposed methodology advantages smaller kidney transplant hospitals disproportionately. The commenter argued that it was impractical to require a larger kidney transplant hospital, already performing over 400 transplants annually, to do an additional 200 or more transplants to earn full points and could not be done without compromising quality of care and patient safety. The same commenter also noted that acquiring the necessary staff, space, and resources to accommodate such a rapid and significant increase would pose a substantial obstacle.

Commenters also raised specific concerns over the proposal to trend the transplant target forward by the national growth rate, as described in section III.C.5.c(1) of this final rule. Many commenters indicated that the more an IOTA participant increases its transplant volume, the harder it will be for them to achieve their transplant target in the future PY because the methodology, as proposed, also trends the baseline transplant volume forward

[199] Potluri, V.S., & Bloom, R.D. (2021). *Effect of Policy on Geographic Inequities in Kidney Transplantation. https://doi.org/10.1053/j.ajkd.2021.11.005;* Hanaway, M.J., MacLennan, P.A., & Locke, J.E. (2020). Exacerbating Racial Disparities in Kidney Transplant. *JAMA Surgery, 155*(8), 679. *https://doi.org/10.1001/jamasurg.2020.1455.*

each PY. Many commenters suggested that IOTA participants may be unfairly penalized for responding to the model's goals and incentives. Specifically, that if IOTA participants meet their transplant target during a performance year, the rising national growth rate could make transplant targets harder to achieve in future PYs. A couple commenters suggested that the growth rate should be regionally indexed or calculated separately by region because regional factors affect the potential for increased transplantation. Lastly, a commenter recommended that CMS determine the national growth rate by calculating the average growth rate across multiple baseline years instead of the proposed approach. This commenter believed that this alternative approach for calculating the national growth rate would take into consideration the natural variability in the annual volume of both living and deceased donor transplants performed at kidney transplant hospitals, resulting in a transplant target that may be more attainable for IOTA participants.

Response: Given the numerous concerns from stakeholders regarding the proposed methodology for calculating transplant targets, we recognized an updated methodology may be necessary to strengthen the model. As indicated in the proposed rule (89 FR 43518) and discussed in the preamble of this final rule, we considered setting each IOTA participant's transplant target by determining the IOTA participant's average total kidney transplant volume from the three previous years instead of using the sum of the highest living and deceased donor kidney transplant volumes during the baseline years. Ultimately, we decided against this approach, as we did not believe it would accurately reflect the IOTA participants' full transplant capacity. Instead, we constructed, and proposed, a methodology to illustrate the individual capabilities and capacities of the IOTA participants, which when combined, would serve as an appropriate transplant target for the program year. However, we recognize that there may be a better balance in including a simpler methodology and result in a transplant target that is potentially more attainable for IOTA participants, assuming that the average kidney transplant volume is lower than the sum of the highest volumes of deceased and living donor kidney transplants while still limiting complexity.

We conducted additional analysis that examined one of the methodologies that we considered for calculating the transplant target as described in section III.C.5.c(1) of the proposed rule. Specifically, based on public comment, we reexamined setting each IOTA participant's transplant target by determining the IOTA participant's average total kidney transplant volume from the three previous years instead of using the sum of the highest living and deceased donor kidney transplant volumes during the baseline years (89 FR 43518). Using historical transplant data, we compared this methodology to what we proposed, as described in this final rule, to determine whether an alternative methodology for setting the transplant target would be potentially more attainable.

Based on additional analysis and the commenters concerns about the proposed transplant target methodology, we are finalizing an updated methodology for setting transplant targets as follows:

For each PY, CMS will calculate the transplant target for the achievement domain by first determining the mean of the total number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older across the baseline years, as defined and finalized in § 512.402 of this final rule.

The mean number of deceased donor and living donor transplants across the baseline years of the IOTA participant would then be projected forward by the national growth rate, as described in section III.C.5.c(1) of this final rule, or zero should the national growth rate be negative, resulting in the transplant target for a given PY.

For example, to calculate the national growth rate for PY 1 using the proposed model start date of January 1, 2025, CMS would first subtract the total number of kidney transplants furnished to patients 18 years of age or older in 2022 from the total number of kidney transplants furnished to patients 18 years of age or older in 2023. Next, CMS would then divide that number by the total number of kidney transplants furnished to patients 18 years of age or older in 2022 to determine national growth rate. To create the transplant target for each IOTA participant for the relevant PY CMS would do the following: 1. If the national growth rate is positive, CMS would trend the national growth rate forward for an IOTA participant by multiplying the national growth rate by the mean number of deceased donor and living donor transplants furnished to patients 18 years of age or older across the baseline years for the IOTA participant.

2. CMS would take the product of step 1 and add it to the mean number of the highest living donor and deceased donor kidney transplants furnished to patients 18 years of age or old across the baseline years for an IOTA participant.

3. The sum of step 2 would be the transplant target for an IOTA participant. However, if the national growth rate were negative, CMS would not trend the growth rate forward for PY 1 and the transplant target would be the sum of the mean number of living donor and deceased donor kidney transplants across the baseline years. For example, when determining individual transplant targets for PY 1 of the model, if an IOTA participant had a mean of 50 living donor and deceased donor kidney transplants furnished to patients 18 years of age or older across the relevant baseline years, and the national growth rate was negative, then the transplant target for that IOTA participant would be 50.

However, we will monitor IOTA participant performance throughout the model performance period and, if warranted, will propose alternative or updated policies in future notice and comment rulemaking.

Comment: Commenters encouraged CMS to reconsider how the proposed transplant target is calculated and suggested a variety of alternative options. Many commenters urged CMS to set each IOTA participant's transplant target by determining the IOTA participant's average total kidney transplant volume from the three previous years. Several of these commenters urged CMS to set each IOTA participant's transplant target by determining the IOTA participant's average total kidney transplant volume from the three previous years across the relevant baseline years. Specifically, a commenter believed that using the average number of transplants across the relevant baseline years would ensure that transplant programs are not penalized for their efforts in increasing transplant volumes prior to program initiation. Another commenter expressed concern that the proposed approach does not take into account the natural year-to-year variability in overall and living donor and deceased donor volume of transplants performed within a kidney transplant hospital. Thus, they recommended that each IOTA participant's transplant target be calculated by determining the IOTA participant's average total kidney transplant volume from the three previous years. The commenter stated that the three-year averaging approach is frequently used by the Innovation Center in other payment methodologies, which could help reduce year-to-year variability and mitigate the impact of potential outliers for transplants from

deceased or living donors in a given year.

A couple commenters suggested CMS use the average kidney transplant volume and a fixed baseline. Specifically, a commenter felt that using the average kidney transplant volume would be more reflective of an IOTA participant's expected performance. A commenter also recommended that CMS take the average of kidney transplant volumes over a 5-year historical period, as it would more accurately reflect past performance. Another commenter believed that the transplant target should be calculated based on the average number of kidney transplants performed during a fixed historical period to ensure that IOTA participants are not penalized for their success in increasing transplant volumes.

A commenter also suggested that CMS select the year with the highest total volume of living and deceased donor kidney transplants combined in relation to the three prior years as the historical benchmark. The commenter felt that this was especially crucial if the historical benchmark is then multiplied by a national growth rate, as proposed, to ensure IOTA participants have a realistic chance of meeting the target. This same commenter also suggested that CMS could consider identifying in the relevant baseline years the highest number of combined deceased donor and living donor kidney transplants and then measure and reward subsequent growth in each transplant type, deceased donor and living donor. However, the commenter acknowledged that this methodology would be more complex and move away from the simplicity originally proposed, which is a strength of the model. Finally, a commenter recommended that CMS use a weighted benchmark based on the actual number of kidney transplants for three years, with the most recent year being weighted the most.

Response: We appreciate the commenters' suggestions on alternative methodologies for setting the transplant target. As mentioned in comment responses noted previously, we recognize that there could be a more favorable balance by adopting a simpler methodology that could result in a transplant target that is more feasible for IOTA participants, assuming that the average kidney transplant volume is lower than the total of the highest volumes from both deceased and living donor kidney transplants, while still keeping complexity to a minimum. As such, we are finalizing an updated methodology for setting transplant targets at § 512.424(b). Specifically, CMS will calculate the transplant target for the achievement domain by first determining the mean of the total number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older across the baseline years, as defined and finalized in section III.C.3.c of the preamble in this final rule.

Comment: A couple commenters suggested that CMS create a fixed baseline year period, rather than changing the baseline every PY. For example, one of these commenters stated that a permanent baseline would be particularly beneficial for larger institutions, for which year-over-year growth is more difficult. Another commenter felt that CMS should use a fixed baseline year period of five to ten years. The commenter noted that a kidney transplant hospital's annual volume is often limited to factors beyond their control and may vary year to year. Thus, they believed that an average of transplant volumes over a five-to-ten-year period would more accurately reflect a participant's past performance. The same commenter also acknowledged that the model performance years would not factor into an IOTA participant's transplant target calculation until the third PY; however; they argued that transplant target methodology as proposed penalizes IOTA participants for their earlier successes by making it more difficult to exceed the target in the future. Therefore, using a fixed baseline would ensure IOTA participants are able to realistically meet their transplant targets and would not be penalized for variations in transplant volumes.

Response: We thank the commenters for their feedback. As described at 89 FR 43552 in the proposed rule, we considered a static or fixed baseline approach, as it would minimize operational burden for CMS due to less frequent updates to the transplant target and ensure that the model does not set a moving target year-over-year. However, for the reasons described in section III.C.5.c(1) of this final rule, we disagree with the commenters that the baseline years should be fixed. We maintain our belief that the proposed rolling baseline approach, which uses historical kidney transplant volumes pre-dating the model start date through the first two model PYs, ensures a phased-in approach before any improvements made during the model performance period are accounted for in the baseline. Thus, we are finalizing our proposal to calculate the transplant target using the relevant baseline years, as defined and finalized in section III.C.3.c of the preamble in this final rule, as proposed.

Comment: Several commenters raised concerns about using CY 2021 when calculating the IOTA participant specific transplant target. Given that transplant hospitals across the U.S. were impacted by COVID–19 at different points throughout the year, a couple commenters believed that CY 2021 data may inadvertently skew the baseline performance, either increasing or decreasing it, obscuring the true performance of programs required to participate in the IOTA Model. Another commenter conveyed that while they recognized the importance of analyzing past performance over multiple years, they suggested that CMS should concentrate exclusively on CY's 2022 and 2023.

A few commenters argued that CY 2021 was an outlier in various aspects and might not reflect the usual practices, or the current and anticipated practices, of numerous transplant hospitals. These aspects included the COVID–19 pandemic and the change in kidney allocation. These commenters specifically noted that the COVID–19 pandemic had a profound influence on kidney transplant volumes during 2021. They suggested that some transplant hospitals lowered their transplant rates, whereas others actually ramped up their operations. They believed that this situation arose in part because transplant hospitals that conducted fewer transplants allowed for a greater availability of high-quality kidneys for the transplant hospitals that remained operational. Additionally, 2021 was the first year the new KAS250 policy took effect, and transplant hospitals were still adjusting to the significant increase in organ offers.

Response: We thank commenters for their feedback and for raising some concerns about the proposed methodology for setting specific transplant targets. We acknowledge the commenters' concerns regarding the inclusion of CY 2021 in the baseline years as it pertains to setting specific transplant targets. We considered setting the transplant target for IOTA participants based on two baseline years, rather than the proposed methodology of three, as described at 89 FR 43552 in the proposed rule. In light of the commenters' concerns, we considered the potential impact of including CY 2021 in the proposed methodology for setting specific transplant targets, as described in section III.C.5.c(1) of the proposed rule. We still believe that using two baseline years to set a transplant target would make the target more susceptible to

temporary market disruptions or fluctuations, such as those discussed at 89 FR 43552 in the proposed rule, which could result in an inaccurate transplant target that does not accurately reflect the IOTA participant's true volume capabilities. As such, we disagree with excluding CY 2021 from the relevant baseline years when setting specific transplant targets. However, as mentioned in comment responses noted previously in this section, we are finalizing a modified methodology for setting specific transplant targets. Specifically, we are finalizing at § 512.424(b) that CMS would calculate the transplant target for the achievement domain by first determining the mean of the total number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older across the baseline years, as defined and finalized in section III.C.3.c of this final rule. We will analyze and monitor the performance of IOTA participants to ensure they are not unfairly disadvantaged by the model. If our analysis indicates the need for a new or revised policy, we will address it through future notice and comment rulemaking.

Comment: A commenter requested that CMS clarify whether the transplant number used for the transplant target calculation would be based on kidney transplants performed for all payors, or just Medicare kidney transplants.

Response: As discussed in the proposed rule at 89 FR 43550, CMS would calculate the transplant target for the achievement domain by first determining the highest number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older in a single year during the baseline years, as defined in section III.C.3.c. of the proposed rule. We clarify that the transplant target would be calculated based on the number of applicable kidney transplants performed across all payors. However, as mentioned in comment responses noted previously, we are finalizing an updated methodology for setting transplant targets. Specifically, we will be finalizing at § 512.424(b) that CMS would calculate the transplant target for the achievement domain by first determining the mean of the total number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older across the baseline years, as defined and finalized in section III.C.3.c of this final rule. We note that this would still be inclusive across all payors and not just Medicare.

Comment: A commenter suggested that CMS provide each IOTA participant with their transplant target three months or at least one month prior to the start of a performance year rather than by the first day of a performance year. Knowing the transplant target ahead of time will allow participants to prepare for the model.

Response: We appreciate the commenter's suggestion. We note that it is our intent to provide each IOTA participant with their transplant target prior to the first day of each PY. However, we acknowledge that operational delays could occur which is why we proposed to provide each IOTA participant with their transplant target by the first day of each PY. Thus, to account for potential operational delays, we are finalizing as proposed.

Comment: A commenter stated that they did not agree with our proposed definition of national growth rate. Specifically, the commenter disagreed with eliminating low-volume kidney transplant hospitals when assessing the national growth rate. Given transplant programs can close and new transplant programs can enter the market, the commenter felt that the national growth rate should be based on all adult kidney transplants performed in the country as this represents a true reflection of growth in kidney transplants performed. The commenter went on to express that they agreed with CMS that the national growth rate in kidney transplants makes the most sense to use as the basis for the model's growth factor but felt that the national growth rate should reflect the total growth rate in kidney transplants as measured across all adult transplants performed at adult transplant programs (with due consideration of the definition of an IOTA transplant patient).

Response: We appreciate the commenter's suggestion and acknowledge their concerns for excluding kidney transplant hospitals that fall below the low volume threshold from the proposed national growth rate, as defined at 89 FR 43617 in the proposed rule. We note that at 89 FR 43550 we proposed that CMS would calculate the national growth rate by determining the percent increase or decrease of all kidney transplants furnished to patients 18 years of age or older from two years prior to the PY to one year prior to the PY. We also stated at 89 FR 43550 that because the proposed national growth rate includes IOTA participants and non-IOTA participant kidney transplant hospitals, we acknowledged that it could make achieving the transplant target number harder. This is why, if the national growth rate becomes negative for a PY, we proposed treating it as zero and CMS would not apply the national growth rate to project forward the sum of the highest number of deceased and living donor kidney transplants furnished in a single year during the baseline years. However, upon further consideration, CMS agrees with this commenter's suggestion. As such, we will be finalizing a modified definition of national growth rate at § 512.402 to eliminate the exclusion of kidney transplant hospitals that fall below the low volume threshold from the national growth rate calculation.

Comment: A commenter indicated that CMS proposed to calculate the national growth rate by determining the percent increase or decrease of all kidney transplants furnished to patients 18 years of age or older from two years prior to the PY to one year prior to the PY. However, the commenter suggested that CMS should provide clarification around whether the national growth rate would be rounded. Specifically, the commenter wanted to know if, when, and how rounding would be applied to these calculations. Additionally, the commenter also wanted to know if the national growth rate would be rounded, and if so, to what extent. The commenter believed that this is important for the calculation of each IOTA participant's transplant target. The commenter also suggested that providing more clarity here could help improve understanding as the IOTA Model is implemented.

Response: We thank the commenter for highlighting the need for clarity regarding whether any of the proposed calculations for setting a transplant target would be rounded. We clarify that once all calculations for setting a transplant target have been made, CMS would do the following:

- Round the transplant target down for decimals less than 0.500; and
- Round the transplant target up for decimals of 0.500 or greater.

For example, if an IOTA participants transplant target is 57.44, CMS would round the transplant target down to 57. Whereas, if an IOTA participants transplant target was 57.54, CMS would round the transplant target up to 58.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed provisions on setting unique transplant targets for each IOTA participant and the methodology for setting transplant targets, with modification. We are codifying in our regulation at § 512.424(b) that for each PY, CMS will determine the transplant

target for the achievement domain, as proposed.

We are codifying in our regulation at § 512.424(b)(1) that CMS analyzes the baseline years for the relevant PY, without modification. In response to comments received, we are replacing the methodology for setting unique transplant targets we had proposed to use for purposes of determining performance in the achievement domain. Specifically, we are codifying in our regulation in sections § 512.424(b)(1)(i) and (ii) that CMS identifies the mean number of deceased donor kidney transplants furnished by the IOTA participant to patients 18 years of age or older across the relevant baseline years, as defined at § 512.402 and the mean number of living donor kidney transplants furnished by the IOTA participant to patients 18 years of age across the baseline years, as defined at § 512.402.

We are finalizing our regulation at § 512.424(b)(2) that CMS sums the numbers in sections §§ 512.424(b)(1)(i) and (ii), without modification. We are also finalizing as proposed our provisions for calculating the national growth rate at § 512.424(b)(3), calculation of transplant target at § 512.582(b)(4), notification of transplant target at § 512.424(c) and the definitions of transplant target, and pediatric kidney transplant hospitals at § 512.402. In response to public comments, we are finalizing our proposed definition of national growth rate at § 512.402 with slight modification to remove the exclusion of kidney transplant hospitals that fall below a low-volume threshold of 11. Specifically, we are codifying at § 512.402 that national growth rate means the percentage increase or decrease in the number of kidney transplants performed over a 12-month period by all kidney transplant hospitals except for pediatric kidney transplant hospitals, as defined at § 512.402. 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.

(2) Calculation of Points

In section III.C.5.c(2) of the proposed rule, we proposed that the achievement domain would be worth 60 points. We chose this domain for the highest number of points because we believe that driving an increase in the number of transplants should be the main incentive for change in the model. We considered allocating fewer points to this domain, such as 50 points, but we believe that performance in this domain should impact the overall performance score more than the other domains given its centrality to the model.

In section III.C.5.c(2) of the proposed rule, we proposed that an IOTA participant's performance would be assessed relative to their transplant target, with those performing at less than 75 percent of the transplant target receiving no points and those performing at 150 percent of the transplant target or above receiving the maximum number of points (60 points). That is, at the highest end of the scale, IOTA participants performing at or above 150 percent of the transplant target would earn the maximum 60 points, while at the lowest end of the scale, IOTA participants performing at less than 75 percent of the transplant target would earn no points for the achievement domain; performance that falls in between 75 percent and 150 percent of the transplant target may earn the IOTA participant 45, 30, or 15 points in the achievement domain. Table 3 illustrates our proposal for how an IOTA participant's performance would be assessed against its transplant target. We chose 150 percent as the maximum performance level based on the theoretical capability of growth in one year and analysis in trends of transplant over time. We recognized that an IOTA participant might exceed 150 percent of its transplant target, but this was not expected given the investment needed for substantiable transplant infrastructure to consistently support that number of transplants over time.

TABLE 3: PROPOSED ASSESSMENT OF ACHIEVEMENT DOMAIN

Performance Relative to Transplant Target	Lower Bound Condition	Upper Bound Condition	Points Earned
150% of transplant target	Equals 150%	Greater than 150%	60
125% of transplant target	Equals 125%	Less than 150%	45
100% of transplant target	Equals 100%	Less than 125%	30
75% of transplant target	Equals 75%	Less than 100%	15
75% of transplant target	N/A	Less than 75%	0

We stated in the proposed rule that we believe that a methodology based on performance improvement relative to historical performance is important and would allow us to test whether the model's performance-based payments drive increased behavior from IOTA participant, as opposed to just rewarding IOTA participants based on the status quo (89 FR 43518). IOTA participants that are achieving a high rate of kidney transplantation, and already have robust transplant programs at the start, can more easily scale up to achieve the additional growth required for excellent performance under the model. Also, given our statutory requirements to achieve savings, the CMS Office of the Actuary (OACT) estimates, as described in section VI of the proposed rule, suggested that savings would be driven by the effects of increased transplants. We believed that the model's performance-based payments need to be tied to a policy that aims to create and drive Medicare savings.

We considered offering differential credit for transplants by type (89 FR 43518). With this methodology, IOTA participants would receive bonus points and score higher for transplants that fit into categories that lead to more savings, such as living donor kidney transplants (LDK), high KDPI donors, or pre-emptive transplants, compared to other transplants. However, we believed that counting all transplants the same, except for transplants furnished to underserved populations, would maximize flexibility for IOTA

participants in meeting their targets and minimize the potential harm and unintended consequences the alternative system would create.

As an alternative, we considered including gradient points instead of points based on bands (that is, between X and Y) (89 FR 43518). Scoring closer to a performance minimum would result in increased points rather than remaining static throughout the band. We considered the following formula: Percent Performance Relative to Transplant Target * (100/2.5), not to exceed 60 points. However, we decided that a narrower range of results would better differentiate performance among IOTA participants and allow for easier comparison across IOTA participants.

We also considered smaller point brackets of improvement, requiring IOTA participants to achieve a flat number increase of kidney transplants, such as to a 140 percent, 125 percent, or 120 percent, to achieve the highest performance in this category, and asymmetric point brackets that would make the magnitude of performance required to achieve the highest performance rate a flat number increase in addition to a percentage increase (89 FR 43518). However, we wanted the percentage of the transplant target necessary to achieve the highest number of points to be large enough to incentivize behavior while still being achievable.

We also considered improvement-only scoring, based on year-over-year IOTA participant transplant growth, without inclusion of national rates (89 FR 43518). In this methodology, positive improvement rates less than 5 percent would be scored 15 points, rates over 5 percent would be scored 30 points, rates over 20 percent would be scored 45 points, and rates over 50 percent would be scored 60 points. We also considered using combinations of potential transplant target or scoring methods, with the final score being whichever score was highest to ensure low-volume IOTA participants are not penalized and to mitigate unrealistic transplant targets. We considered an improvement-only scoring methodology to reflect the historical performance of each IOTA participant. However, because we want a methodology that sets more of a national standard for expected growth rate to assess volume trends in the transplant space overall, we chose not to propose improvement-only scoring. As organ supply continues to increase year-over-year, we wish to set the expectation for IOTA participants to grow their transplant volumes at least at the cadence of the national growth rate.

We solicited comment on our proposed achievement domain scoring methodology and alternative methodologies considered.

The following is a summary of the comments received on our proposed achievement domain scoring methodology, alternative methodologies considered and our responses:

Comment: Numerous commenters expressed concerns that the achievement domain requires an impractically significant increase in kidney transplant volume, especially in the later PYs of the IOTA Model. In particular, they felt it would be virtually impossible for IOTA participants to earn the maximum points in this domain, and that the proposed approach would undermine the overall model test.

Response: We recognize the validity of this critique from commenters and believe in updating the achievement domain in two key areas. The first is that the transplant target for each IOTA participant will be calculated based on a rolling average of transplants, as described and finalized in section III.C.5.c(a) of this final rule, rather than taking the highest number of living and deceased transplants across the relevant baseline years, as discussed previously. The second is to modify our scoring methodology for allocating points for the achievement domain at Table 1 under § 512.424(f)(2), as illustrated in Table 4 of this section.

Comment: Several commenters expressed concern that the proposed thresholds for increasing transplant rates are aggressive such that they could negatively impact performance score metrics for all IOTA participants, recommending that CMS set more realistic performance goals by lowering the points thresholds in the achievement domain. For instance, a commenter supported the proposed methodology of awarding points based on percentage relative to transplant target thresholds. However, they believed the proposed points thresholds exceeded reasonable expectations for eligible kidney transplant hospitals. The commenter recommended that CMS set the highest points threshold (60 points) at greater than 125 percent of the transplant target, and drop the lowest points threshold (0 points) to less than 50 percent of the transplant target. This, the commenter felt, would ease IOTA participants' ability to receive achievement domain points, help alleviate resource disparities between participant hospitals, and reduce the potential for financial considerations to cloud clinical judgment when matching organs to recipients.

Another commenter recommended that CMS use a volume growth trend that better recognizes the potential limits of transplant programs to expand capacity in a more reliable, realistic, and safe manner. The commenter felt that having a transplant goal that is more achievable would also incentivize the growth the IOTA Model is trying to achieve. Setting transplant targets too high could discourage IOTA participants from growing their kidney transplant programs at all if the targets are unrealistic and not achievable. As such, this same commenter recommended that CMS allow IOTA participants to achieve the maximum 60 points for the achievement domain with performance equal or greater than 110 percent of the transplant target.

Another commenter stated that to achieve a 10 percent increase in kidney transplants, a large-volume kidney transplant hospital performing 400 transplants annually would need to do an additional 40 per year. While the increase would be less for smaller kidney transplant hospitals, any additional transplants may strain their personnel and infrastructure. The commenter also suggested that kidney transplant hospitals of any size need appropriate lead time to estimate and accommodate the increase in transplant volume. Expanding transplant capacity requires significant infrastructures investments, such as for higher-risk candidates and donor organs, infusion bays, access to inpatient and outpatient dialysis for higher volumes of recovering recipients with delayed graft function, and additional personnel. The commenter warned that disregarding these infrastructure needs would put undue stress on the healthcare system and could prevent IOTA participants from meeting mandated targets. For these reasons, they recommended that the achievement domain points thresholds be lowered to a more realistic performance metric (for example, 110 to 125 percent relative to transplant target).

Lastly, a commenter believed that the proposed achievement domain points thresholds are too aggressive and would sharply curtail the opportunity for IOTA participants to achieve more than 30 points in any PY. The commenter suggested an alternative approach that would allow IOTA participants to earn the maximum 60 points in the achievement domain if their performance exceeded the transplant target by 125 percent or more.

Response: We thank the commenters for expressing their concerns and for their suggestions on our proposed methodology for awarding points for performance in the achievement

domain. As described in the proposed rule at 89 FR 43553, we considered smaller point brackets of improvement to achieve the highest performance in this category but chose not to propose smaller point brackets of improvement as we wanted the percentage of the transplant target necessary to achieve the highest number of points to be large enough to incentivize behavior while still being achievable. However, in response to comments received, we are updating the methodology for points allocation in the achievement domain. Specifically, we are finalizing, with modification, Table 1 to Paragraph (f)(2) at § 512.424(f)(2) to reflect the updated points allocation, as illustrated in Table 4.

TABLE 4: ASSESSMENT OF ACHIEVEMENT DOMAIN

Performance Relative to Transplant Target	Lower Bound Condition	Upper Bound Condition	Points Earned
125% of transplant target	Equals 125%	Greater than 125%	60
120% of transplant target	Equals 120%	Less than 125%	55
115% of transplant target	Equals 115%	Less than 120%	50
105% of transplant target	Equals 105%	Less than 115%	40
95% of transplant target	Equals 95%	Less than 105%	30
85% of transplant target	Equals 85%	Less than 95%	20
75% of transplant target	Equals 75%	Less than 85%	10
75% of transplant target	N/A	Less than 75%	0

We believe that the updated scoring system reflects our partial agreement with commenters. Specifically, we are lowering the maximum performance threshold from 150 percent to 125 percent of the transplant target. Moreover, in combination with the updated methodology for setting transplant targets, as described and finalized section III.C.5.c(1) of this final rule, we believe that this revised standard is more achievable for IOTA participants and strikes a balance—it aims to incentivize performance, while also recognizing the challenges that IOTA participants may face in increasing their kidney transplant volume.

Lastly, because we are updating achievement domain performance thresholds and points allocation, we are keeping the performance threshold for earning 0 points at 75 percent of the transplant target as proposed at 89 FR 43553. This is to ensure a minimum level of performance from IOTA participants and keep the focus on ensuring that the number of kidney transplants performed by IOTA participants does not significantly decrease.

Comment: A commenter suggested that CMS adopt a more graduated scoring scale, providing additional opportunities for IOTA participants to earn points in the achievement domain.

Response: We appreciate the feedback from the commenter. As mentioned in comment responses noted previously, in light of the comments received, we are updating the methodology for points allocation in the achievement domain, as illustrated in Table 4 of this section. The updated methodology for point allocation includes additional gradations, which we believe will provide IOTA participants with greater opportunities to earn points compared to the four scoring ranges we originally proposed at 89 FR 43553 in the proposed rule.

Comment: A commenter expressed concerns that the proposed methodology for calculating transplant targets would have compounding negative effects on performance over time, making it increasingly difficult for IOTA participants to earn maximum points in the achievement domain in later years of the model.

Response: We thank the commenter for raising their concern. We recognize that the proposed methodology may have set a standard that may have been too difficult for IOTA participants to meet. We believe that our updated methodology for setting the transplant target, as described and finalized in section III.C.5.c(1) of this final rule, sets a balance between trying to incentivize improvement over time with allowing IOTA participants to recognize the benefits of investment in increasing their number of kidney transplants. Moreover, as described in the proposed rule at 89 FR 43550, the model PYs would not factor into an IOTA participant's transplant target calculation until PY 3 of the model and the baseline years would not be based exclusively on PYs until PY 5 of the model. We maintain our belief that using baseline years to calculate the transplant targets could represent an effective phase-in approach to drive improved performance and savings for the Medicare trust fund, while also accounting for kidney transplant hospitals that experience changes in strategy or staffing that may affect their transplant capacity compared to previous years.

Comment: We received a comment that the only way that IOTA participants can increase their supply is by using marginal organs which would result in increased rates of graft failure for transplanted patients.

Response: We disagree with this commenter and would like to provide clarification. We did not specify how IOTA participants should increase their number of kidney transplants, nor do we believe that the only way that IOTA participants can increase their number of transplants is by using marginal organs. In the proposed rule at 89 FR 43551, we expressed our belief that IOTA participants could improve on this metric and provided several possible ways that they might be able to. We acknowledge that some IOTA participants may choose to increase their utilization of DCD kidneys or kidneys with a KDPI greater than 85, however, the IOTA Model does not prescribe that they do. Additionally, the CoPs for transplant hospitals require that the transplanting surgeon at the transplant program is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient (42 CFR 482.92).

Furthermore, we believe that many organs that are not used today have a clinical profile similar to organs that are ultimately transplanted. As such, we expect that IOTA participants will exercise their medical judgement appropriately when determining whether or not to accept a DCD kidney organ offer.

Comment: We received a comment that there is not enough available transplant supply to increase numbers, particularly at the thresholds that CMS set in the proposed scoring for the achievement domain.

Response: We believe that the updated transplant target methodology and scoring methodology make the transplant targets more achievable for IOTA participants. We also recognize the growth in organs being procured by OPOs since the 2020 CfC update and believe that there is an opportunity for transplant hospitals to take advantage of the updated supply being procured by OPOs. Additionally, we believe that living donation represents an untapped supply of potential kidney transplants that is not dependent on procurement practices.

Comment: A commenter expressed their disagreement with the proposed achievement domain performance thresholds, as they do not take into account the inability of transplant programs to scale up the volume of the number of transplants performed in a given year. The commenter believed that some transplant programs may have excess capacity to perform more transplants annually, but others would face significant fixed costs to expand their transplant operations beyond their current volume. Additionally, the commenter noted that in the current labor market, it would be challenging to recruit and retain the highly specialized staff, including transplant physicians, needed to expand the capacity of their transplant program to meet these transplant targets.

Response: We recognize that there will be some need for IOTA participants to scale up, which is why we are not finalizing the proposed model start date of January 1, 2025. As described and finalized in section III.C.1.a of this final rule, we are finalizing a model start date of July 1, 2025. We also note that there is no downside risk payment in PY 1, as described and finalized in section III.C.6.c(2)(b) of this final rule. As such, it will be over 18 months from the publication of this final rule until an IOTA participant is held liable for their number of transplants with the potential for a downside risk payment. Furthermore, as mentioned in comment responses in this section, we will be finalizing an updated methodology for points allocation in the achievement domain, as illustrated in Table 4 in this section, and our methodology for setting transplant targets, as described and finalized in section III.C.5.c(1) of this final rule. For these reasons, we believe this will give time for IOTA participants to make investments to expand their transplant program, resulting in a transplant target that is potentially more attainable for IOTA participants and providing additional opportunities to be awarded points.

Comment: Multiple commenters expressed concern that the proposed scoring methodology was too difficult for large kidney transplant hospitals, given that a significant percentage increase for them represents a higher number of additional transplants. We also received comments pointing out that the scoring methodology could be punitive to IOTA participants that already invested to increase their number of transplants before the start of the model.

Response: We thank the commenters for expressing their concerns regarding the proposed scoring methodology. We note that, as described and finalized in section III.C.5.c(1) of this final rule, that we are finalizing an updated methodology for setting transplant targets. We direct readers to section III.C.5.c(1) of this final rule for further discussion on our updated methodology for setting transplant targets. As such, we believe that this updated methodology for setting transplant targets will make top performance in the achievement domain more achievable for all kidney transplant hospitals participating in the model. We also recognize that larger kidney transplant hospitals have already invested in additional capacity and resources to help more patients through the transplant process, which means that they have experience in increasing their transplant numbers that they can leverage as IOTA participants.

Comment: We received comments that the proposed scoring methodology was too difficult for smaller kidney transplant hospitals. Commenters pointed out that smaller kidney transplant hospitals may experience fluctuations in their transplant volume. Given their lower volume of kidney transplants, a small numerical decrease in the number of kidney transplants they perform could translate to a large percentage drop, potentially resulting in a loss of all points in the achievement domain.

Response: We believe that the updated methodology for setting transplant targets, as described and finalized in section III.C.5.c(1) of this final rule, will help smaller kidney transplant hospitals selected to participate in the model deal with fluctuations. We direct readers to section III.C.5.c(1) of this final rule for further discussion on our updated methodology for calculating transplant targets. The updated scoring methodology, as shown in Table 4, will provide more gradation in scoring. As such, we believe that this should prevent small kidney transplant hospitals from being significantly impacted if they fall short of their transplant targets by a small margin. The increased number of scoring thresholds means IOTA participants will have more opportunities to earn points, minimizing the effect of minor shortfalls.

Comment: Several commenters proposed including a living donor performance adjustment, which would award additional points for living donor kidney transplants. A commenter suggested that, in the absence of adequate risk adjustment, a performance adjustment, similar to the proposed health equity adjustment, with a weighting greater than 1 should also be considered for living donor transplants. Another commenter suggested that CMS should consider including an incentive multiplier in the achievement domain point calculation for living donor kidney transplants, as this is the optimal treatment for patients with end-stage kidney disease (ESKD). Lastly, a commenter praised CMS's efforts to improve the organ transplantation system, but recommended giving greater weight to living donor kidney transplants over deceased donor kidneys for several reasons. For example, the commenter cited that living donor kidneys typically have a lower risk of graft failure compared to deceased donor kidneys. This results in longer lifespans for living donor kidney recipients, fewer complications, better post-transplant outcomes, and reduced burden on the healthcare system—ultimately enhancing overall patient health. Additionally, they noted that there is a reduced need for immunosuppressive medications because patients receiving a living donor kidney often require less immunosuppressive drugs. For these reasons, the commenter proposed that CMS either assign a larger weight to living donor kidney transplants or apply a multiplier akin to the proposed health equity performance adjustment.

Response: We thank the commenters for their suggestions to include a living donor performance adjustment. We recognize the benefits of living donor

transplantation and views it as an important part of the transplant process. However, the IOTA Model test prioritizes flexibility, allowing IOTA participants to determine the best way to perform. We also acknowledge that IOTA participants may have varying comfort levels with promoting living donation. As such, we want to prioritize flexibility for IOTA participants rather than specifically promoting any particular transplant type. Additionally, we believe that the composite graft survival rate measure, as described and finalized in section III.C.5.e(1) of this final rule, in the quality domain accounts for the potential long-term survival benefits of living donation for patients.

Comment: A commenter suggested that IOTA participants receive additional points in the proposed achievement domain scoring methodology for preemptive kidney transplants, as they offer considerable survival and quality of life benefits for patients, as well as major cost savings. Given the substantial benefits to patients and the substantial savings as compared to dialysis, the commenter recommended that CMS consider creating a preemptive bonus or preemptive multiplier, which could be scaled proportionately with savings to the Medicare program pre-emptive transplants provide relative to maintenance dialysis. However, the commenter emphasized that carefully calibrating and closely monitoring such a bonus or multiplier would be crucial. Ideally, this process should involve input from the community to ensure the incentive expands access to pre-emptive kidney transplants rather than exacerbating existing disparities.

Response: We thank the commenter for their suggestion but disagree with the commenter. We recognize the benefits of preemptive transplantation. However, we are unsure whether the inclusion of a preemptive kidney transplant performance adjustment would be effective at incentivizing preemptive transplantation. We plan to monitor the effects of the model on preemptive transplantation as part of the evaluation process and may consider potential changes to the model through future notice and comment rulemaking, depending on performance by IOTA participants.

Comment: A couple commenters suggested that CMS should use two metrics to score IOTA participants in the achievement domain: percentage growth in kidney transplants and a flat threshold for increased kidney transplant volume. For instance, a commenter proposed that IOTA participants earn maximum points if they achieve 150 percent of their transplant target or perform 25 additional kidney transplants.

Response: We thank the commenters for their suggestions to include an additional flat threshold scoring methodology. We understand the merits of this idea as it recognizes that it may be more difficult for IOTA participants that are already performing more transplants to further increase their number of transplants. As described at 89 FR 43553 in the proposed rule, we considered a methodology based on year-over-year IOTA participant transplant growth, excluding national growth rates. We also considered using combination of potential transplant target or scoring methodologies, taking the highest resulting score to avoid penalizing low-volume IOTA participants and prevent unrealistic transplant targets. However, for the reasons described in section III.C.5.c(2) of this final rule, we chose not to propose either of the methodologies discussed previously.

We believe that the updated methodology for setting transplant targets, as described and finalized in section III.C.5.c(1) of this final rule, and the updated scoring methodology in the achievement domain, as illustrated in Table 4 in comment responses noted previously, will make it more achievable for IOTA participants of all sizes to achieve maximum points in this domain.

Comment: A commenter expressed their concern over the number of proposed points for the achievement domain (60 points) and quality domain (20 points). Specifically, the commenter was concerned that, in the context of resource scarce kidney transplant hospitals, resources would be pulled from efforts to help patients succeed in the long-term (post one-year) period in order to deliver success on increasing transplant rates. As such, the commenter believed that greater emphasis was needed to encourage focus on, and investment in, supporting patients' longer-term (post-one-year and longer) outcomes post-transplant, recommending that CMS allocate a maximum of 50 points for the achievement domain instead of the proposed 60 points.

Response: We appreciate the commenter's recommendation and acknowledge their concerns. The achievement domain performance score was weighted more heavily than the efficiency and quality domains because we believe this aligns with the IOTA Model's primary objective of increasing the total number of kidney transplants (89 FR 43548). Moreover, recognizing that the main goal of the model is to increase the number of kidney transplants performed, we maintain that weighing performance on this measure more than the efficiency domain and quality domain is necessary to directly incentivize participants to meet their target, as increasing the number of kidney transplants performed is the primary goal of the model. For these reasons, we disagree with the commenter that CMS should decrease the number of proposed points allocated for the achievement domain and are finalizing our proposal to allocate 60 out of a maximum 100 points to the achievement domain, as described and finalized in section III.C.5(b) of this final rule. Regarding our proposed point allocations across the achievement domain, efficiency domain, and quality domain, and alternatives we considered, we direct readers to section III.C.4.b of this final rule. We note that we intend to monitor the impacts of the quality domain and efficiency domain throughout the model test and will consider whether adjustments in the maximum number of points awarded in each domain are necessary in future notice and comment rulemaking.

After consideration of the public comments, for the reasons set forth in this rule, we are finalizing our proposed achievement domain scoring methodology, with modification. As described in section III.C.5.c(3) of the preamble in this final rule, we will not be finalizing a health equity performance adjustment provision. As such, we are finalizing the provisions at § 512.424(a) with slight modification. Specifically, we are modifying the regulatory text at § 512.424(a)(2) to remove references to a health equity performance adjustment and make minor technical corrections in punctuation.

We are codifying in our regulation at § 512.424(f) that for each PY, CMS awards the IOTA participant zero to 60 points for its performance in the achievement domain, as proposed. We are also making a minor technical correction to update the cross reference in our regulation at § 512.424(f)(1). In particular, we are removing the cross reference to the health equity performance adjustment and replacing it to reflect § 512.424(d)(2). We direct readers to section III.C.5.c(3) of this final rule for further discussion on the health equity performance adjustment.

We are also finalizing § 512.424(f)(2) as proposed, which states that for each PY, CMS will calculate the transplant target for the achievement domain, as proposed. Lastly, in response to

comments received, we are replacing the methodology for points allocation in the achievement domain. Specifically, we are finalizing, with modification, Table 1 to Paragraph (f)(2) at § 512.424(f)(2) to reflect the updated points allocation, as illustrated in Table 4 above. However, we will 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) Health Equity Performance Adjustment

Socioeconomic factors impact patient access to kidney transplants. Patients with limited resources or access to care may require more assistance from kidney transplant hospitals to overcome barriers to transplantation. To incentivize IOTA participants to decrease disparities in the overall transplant rate among patients of various income levels, we proposed to include a health equity performance adjustment in the methodology for calculating the overall number of transplants furnished to patients attributed to an IOTA participant during the PY. We proposed to define the ''health equity performance adjustment'' as the multiplier applied to each kidney transplant furnished to a low-income population IOTA transplant patient when calculating the transplant target (as described in § 512.424 of the proposed rule). For purposes of the model, we proposed to define the ''low-income population'' to mean an IOTA transplant patient in one or more of the following groups:

- The uninsured.
- Medicaid beneficiaries.
- Medicare-Medicaid dually eligible beneficiaries.
- Recipients of the Medicare low-income subsidy.
- Recipients of reimbursements from the Living Organ Donation Reimbursement Program administered by the National Living Donor Assistance Center (NLDAC).

In the proposed rule, we proposed to apply a health equity performance adjustment, a 1.2 multiplier, to each kidney transplant furnished by an IOTA participant to a patient, 18 years of age or older at the time of transplant, that meets the low-income population definition. That is, each kidney transplant that is furnished to a patient who meets the low-income population definition would be multiplied by 1.2, thus counting that transplant as 1.2 instead of 1. The resulting count of the overall number of kidney transplants performed during the PY, after the health equity performance adjustment is applied, would then be compared to the transplant target. In effect, the health equity performance adjustment would be a reward-only adjustment to the performance score in the achievement domain. We also considered basing the multiplier on the difference between rates of transplantation for Medicare beneficiaries with ESRD who are dual eligible and those who are not. In 2019, 47 percent of Medicare beneficiaries with ESRD were dually eligible for Medicare and Medicaid. However, only 41 percent of Medicare transplants recipients were dually eligible, which would yield a multiplier of 1.1.[200]

We chose 1.2 as the health equity performance adjustment multiplier because, according to USRDS data, 78.6 percent of patients living with ESRD have some form of Medicare and or Medicaid coverage; however, only 65.1 percent of patients who received transplants in 2020 were on Medicare, Medicaid, or both.[201] [202] The 1.2 multiplier represents the ratio of those living with ESRD and those who received transplants. We theorized that providing this incentive for IOTA participants to increase their transplant rate among low-income populations would ultimately reduce disparities in access to kidney transplants, as it would encourage IOTA participants to address access barriers low-income patients often face, such as transportation, remaining active on the kidney transplant waiting list, and making their way through the living donation process.

We believed that the health equity performance adjustment would be a strong incentive to promote health equity, as the multiplier earned would help IOTA participants meet or exceed their kidney transplant target, thereby potentially resulting in upside risk payments given the heavy weighted scoring applied to the achievement domain. We also believed it would ensure IOTA participants that serve disproportionately high numbers of low-income populations are not penalized in the achievement performance scoring.

We considered not applying a health equity performance adjustment to the achievement performance scoring, which would ensure all kidney transplants, regardless of the low-income status of individual patients, are counted as one transplant. The concern with the health equity performance adjustment may be that it may incentivize shifting of kidney transplants from one type of patient to another. However, we believed the incentive is to promote improvement activities that would increase access to all patients while recognizing that low-income patients may face more barriers to care outside of the IOTA participants' control. It also recognizes that disparities already exist in access to kidney transplants for low-income patients, so, by addressing inequities, IOTA participants would focus efforts on tackling inequities for patients outside the Medicare population.

For purposes of the health equity performance adjustment, we also considered using the area deprivation index (ADI) to define the low-income population. ADI ranks neighborhoods based on socioeconomic disadvantage in the areas of income, education, employment, and housing quality. Areas with greater disadvantage are ranked higher, and they correlate with worse health outcomes in measures such as life expectancy.[203] The areas used in the ADI are defined by Census Block Group, which presents a number of challenges.[204] However, because address information for Medicare beneficiaries may be incomplete, and not available at all for patients who have private insurance or the uninsured, we opted to not use ADI to define the low-income population. We believed that this would leave an incomplete picture of the transplant population for a given IOTA participant. Furthermore, the socioeconomic status of individuals within a given ADI can vary greatly. Those that are underserved in a Census Block Group with a low ADI may be overlooked.

We also considered including ''rural resident'' as one of the groups that define a low-income population in the IOTA Model, as rural transplant patients face numerous barriers to care, including transportation, food, housing, and income insecurity, and no or

[200] Gillen, E.M., Ganesan, N., Kyei-Baffour, B., & Gooding, M. (2021, August 30). *Avalere analysis of disparities in Kidney Care Service Utilization.* Avalere Health. *https://avalere.com/insights/avalere-analysis-of-disparities-in-kidney-care-service-utilization.*

[201] United States Renal Data System. (2020). *2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases.* Bethesda, MD.

[202] Lentine, K.L., Smith, J.M., Hart, A., Miller, J., Skeans, M.A., Larkin, L., Robinson, A., Gauntt, K., Israni, A.K., Hirose, R., & Snyder, J.J. (2022). OPTN/SRTR 2020 Annual Data Report: Kidney. *American Journal of Transplantation, 22*(S2), 21–136. *https://doi.org/10.1111/ajt.16982.*

[203] *Neighborhood Atlas—Home.* (2018). *Wisc.edu. https://www.neighborhoodatlas.medicine.wisc.edu/.*

[204] *https://www2.census.gov/geo/pdfs/reference/GARM/Ch11GARM.pdf.*

limited access to kidney transplant hospitals within or close to their rural communities. We considered defining rural beneficiaries consistent with the criteria used for identifying a rural area when determining CAH eligibility at 42 CFR 485.610(b)(1)(i), that is, beneficiaries living outside an MSA. However, we were unsure if it was appropriate to include this group to define a low-income population to determine if a health equity adjustment would apply to the achievement performance score, particularly as the proposed low-income definition may already capture the majority of rural kidney transplant patients.

We sought comment on our proposed health equity performance adjustment, including on the adjustment multiplier and calculation method, the definition of low-income population and alternatives considered, including consideration of ADI as an alternative definition, or including rural resident in the low-income population definition.

The following is a summary of the comments received on our proposed health equity performance adjustment, including on the adjustment multiplier and calculation method, the definition of low-income population and alternatives considered, including consideration of ADI as an alternative definition, or including rural resident in the low-income population definition and our responses:

Comment: A couple commenters advised CMS against finalizing the proposed HEPA provision for a variety of reasons, arguing that it prioritizes non-medical factors and prompts IOTA participants to unfairly favor certain patients over others for reasons unrelated to clinical needs.

Response: We appreciate the feedback from commenters, but we respectfully disagree with their position. We originally proposed this provision out of concern for the existing disparities in access to transplants. The proposed HEPA was not intended to incentivize a focus on any particular patient group, but rather to encourage kidney transplant hospitals to identify and address the barriers faced by their underserved patient populations, with the goal of overcoming issues related to SDOH. Moreover, we believe that IOTA participants will leverage their medical expertise to deliver the best outcomes for patients. However, in light of all the comments we received and about the potential for unintended consequences, we will not be finalizing the proposed HEPA at this time. As part of the evaluation process, we intend to monitor how the model impacts low-income individuals' access to kidney transplants and may consider proposing a new or updated policy through future notice and comment rulemaking.

Comment: While a commenter appreciated CMS' focus on promoting health equity in this model, they did not support the proposed HEPA due to broader concerns about using transplant volume as a performance measure. Specifically, the commenter noted that although the HEPA aims to encourage IOTA participants to provide transplants for uninsured patients, the bonus payments are insufficient to cover the extensive, long-term care required for successful transplant outcomes. Transplant patients need a wide range of services beyond just the surgery itself, including preoperative testing and monitoring, dietary counseling, and ongoing medications. However, a lack of insurance coverage presents a major challenge for both patients and kidney transplant hospitals in achieving better kidney care outcomes. For these reasons, the commenter argued that CMS' proposed health equity multiplier approach to incentivize organ transplantation services for underserved patients is an inadequate solution to this complex issue.

Response: We appreciate the feedback and believe that the increased payment amounts in the model could provide additional resources for IOTA participants to support the necessary interventions required to overcome barriers for underserved patients. However, as mentioned in comment responses noted previously in this section, we will not be finalizing the HEPA as we are concerned about the potential for unintended consequences and will keep this feedback in mind as we consider alternatives in future notice and comment rulemaking.

Comment: A commenter expressed concern that the proposed HEPA incentivizes out-of-sequence allocation of kidneys by IOTA participants, giving preferential treatment to low-income candidates, in order to maximize the number of points they receive in the achievement domain. Given these concerns and the pressing disparities in access to living donor transplants, the commenter urged CMS to consider increasing the HEPA, but limiting the availability of the HEPA to living donor transplants.

Response: We appreciate this feedback. As mentioned in commented responses previously in this section, we will not be finalizing the proposed HEPA at this time. Additionally, as described and finalized in section III.C.13.c of this final rule, we will monitor the rates of out-of-sequence allocation that may result from the model. This is to ensure the model does not have unintended consequences. Accordingly, we do not anticipate any potential impact of out-of-sequence allocation as a way to prioritize transplants for underserved populations.

Comment: A commenter strongly agreed with CMS' intended goal of using financial incentives to encourage IOTA participants to improve health equity and reduce disparities in overall transplant rates for lower-income patients. However, the commenter expressed significant concerns about the potential unintended consequences of this design. Specifically, they believed that financially incentivizing the use of lower-quality kidneys for lower-income patients, while also incentivizing more transplants for this group, could inadvertently link these factors and entrench a two-tiered system. The commenter stated that this could result in lower-income patients being offered lower-quality kidneys, further exacerbating health disparities among kidney transplant recipients. Additionally, the commenter was concerned that while the proposed model would increase kidney transplantation rates for those already on the waitlist, it overlooked the broader barriers in healthcare access that prevent low-income patients from being placed on the transplant waitlist in the first place. As such, the commenter recommended that CMS not finalize the HEPA.

Response: We thank the commenter for sharing their support and concerns. We acknowledge potential concerns about the proposed HEPA policy, but also recognize the substantial benefits of kidney transplantation over dialysis, even for complex organs. Furthermore, we believe IOTA participants will exercise their medical expertise to ensure the best possible outcomes for patients. However, as mentioned in comment responses noted previously in this section, we will not be finalizing the proposed HEPA provision at this time due to the potential for unintended consequences. We intend to monitor how the model impacts low-income individuals' access to kidney transplants and may consider proposing a new or updated policy through future notice and comment rulemaking.

Comment: A commenter suggested that the proposed HEPA would bias IOTA Model results toward larger kidney transplant hospitals with the financial resources to overcome the challenges of serving low-income patients. The commenter also believed that any effort to shift transplantation decisions away from purely clinical

considerations would necessarily produce adverse results, such as higher rates of unsuccessful transplants. Specifically, IOTA participants may take greater risks by transplanting kidneys into HEPA-eligible patients rather than better clinically-matched recipients, leading to increased failure rates. For these reasons, the commenter strongly recommended that CMS reduce the multiplier for the HEA from 1.2 to 1.05 or 1.1. Additionally, the commenter suggested lowering the achievement domain points thresholds commensurately, setting the highest threshold (sixty points) at greater than 125% of target and dropping the lowest (zero points) to less than 50% of target. This, they believed, would help address the resource gap between IOTA participants. Additionally, the commenter felt this change would also reduce the potential adverse consequences of clouding clinical judgment with financial considerations when matching organs to recipients. Finally, the commenter noted that making these suggested changes would further recognize the sometimes-severe disparity of available organs from one PY and its relevant baseline years to the next.

Response: We thank the commenter for sharing their concerns; however, we disagree that the proposed HEPA would bias larger kidney transplant hospitals. We believe all transplant hospitals, not just larger ones, should focus on overcoming barriers for underserved populations. Moreover, many of the interventions needed to address these barriers are covered by organ acquisition costs. However, in response to the public comments we received on our proposed HEPA, we will not be finalizing this provision at this time.

Comment: Several commenters urged CMS to include rural residents as a population group in the proposed definition of low-income population that is eligible for the proposed HEPA; given the limited access to transplant services in rural areas and additional challenges that rural residents, regardless of income, face throughout the transplant process. For example, a commenter appreciated that CMS considered including rural residents in the proposed low-income patient definition eligible to receive the proposed HEPA. However, the commenter urged CMS to reconsider this factor, arguing that it would help address the unique challenges rural residents face throughout the transplant process. Another commenter recommended that CMS consider including ''rural resident'' as a group in the proposed definition of low-income population for the purposes of the IOTA Model, since rural residency is associated with significant barriers to transplantation, a situation only made worse by the increasingly precarious hospital footprint in rural areas of the country. Due to the significant barriers to transplantation faced by rural residents, which are exacerbated by the increasingly limited availability of hospitals in rural areas, a commenter recommended that CMS should include rural resident as a group in the proposed low-income population definition for the IOTA Model.

A commenter strongly supported the proposed HEPA and applauded CMS for recognizing that some patients require more assistance from kidney transplant hospitals to overcome barriers to transplantation. This commenter felt CMS correctly identified that rural transplant patients face barriers to care, some of which are income related such as food, housing, and income insecurity. The commenter believed that patients facing these barriers would almost certainly qualify for the proposed health equity performance adjustment (HEPA) through Medicaid eligibility or the Medicare Low Income Subsidy (LIS). According to the commenter, patients confronting these barriers would likely qualify for the proposed HEPA through Medicaid eligibility or the Medicare Low Income Subsidy (LIS). However, the commenter stated that they could attest that two of the barriers identified by CMS—transportation issues and ''limited access to kidney transplant hospitals within or close to rural communities''—complicate transplant care for patients, regardless of their income level. The commenter argued that by including rural residents in the groups qualifying for the proposed HEPA, CMS would ensure that the additional assistance kidney transplant hospitals must provide to help rural patients of all income levels overcome barriers to transplantation is properly accounted for. Lastly, this commenter stated their belief that the criteria used for identifying a rural area when determining CAH eligibility at 42 CFR 485.610(b)(1)(i) would sufficiently capture rurality.

Lastly, a commenter greatly supported CMS' efforts to strengthen health equity in value-based care, but believed CMS should expand the proposed definition of low-income population eligible for the HEPA to also include rural residents, given the limited access to transplant services in rural areas. The commenter argued that rural patients face significant barriers to accessing transplant services, as they are less likely to be added to transplant waitlists or referred for transplant by dialysis providers due to the limited availability of transplant services in rural areas. Therefore, the commenter felt CMS should incentivize IOTA participants to care for rural patients through the HEPA for low-income populations, in order to address the disproportionate challenges faced by the rural population in accessing transplant care. The commenter suggested that if CMS is hesitant to label all rural patients as low-income, they could rename the adjustment to more accurately reflect the vulnerable populations it includes.

Response: We thank the commenters for their support and recommendation to include rural residents in our proposed definition of low-income population eligible to receive the proposed HEPA. We recognize that rural patients may face additional barriers and challenges throughout the transplant process. However, as mentioned in comment responses noted previously, we will not be finalizing the proposed HEPA at this time. Additionally, we will consider additional adjustments to the model that may account for the barriers faced by patients living in rural areas in future notice and comment rulemaking.

Comment: A commenter noted that they have dialysis patients that get assistance to enroll in commercial plans. The commenter argued that these individuals should be classified as low-income, citing their frequent socioeconomic barriers, and urged CMS to revise the proposed definition of low-income population to encompass these individuals.

Response: We thank the commenter for their suggestion. We chose the specific designations in an effort to use insurance status as a proxy for underserved status for beneficiaries and the statuses we proposed at 89 FR 43553 in the proposed rule (uninsured, Medicaid beneficiaries, Medicare-Medicaid dually eligible beneficiaries, recipients of the Medicare LIS, or recipients of reimbursements from the Living Organ Donation Reimbursement) only apply to lower-income beneficiaries, whereas beneficiaries with commercial insurance may not be low-income. As such, we disagree with the commenter.

Comment: A commenter expressed strong support for reducing health inequities but felt that the proposed methodology for identifying low-income populations, although clear, may not be comprehensive in gathering the intended information. Specifically, the commenter cited three concerns: (1) The commenter was unaware of transplant hospitals that would knowingly

transplant someone without insurance who lacked the means to cover the costs out-of-pocket. Therefore, the uninsured criteria may identify patients with significant means, unless CMS examines people who have lost some or all insurance after transplant.; (2) Transplant hospitals do not know which patients receive LIS benefits, and many patients are unaware that they receive this benefit, based on the commenter's experience.; and (3) NLDAC benefits are attached to the donor, not the recipient, so CMS may not have access to this information.

Response: We thank the commenter for their feedback. We believe that all patients with kidney disease deserve equitable care and access to the transplant process. We urge transplant hospitals to think about how to overcome barriers for patients, regardless of insurance status, and to think about how to best care for patients' needs. Although we will not be finalizing the proposed HEPA at this time, we will consider the comments that were received during the public comment period and may make future proposals during the course of the model test in future notice and comment rulemaking.

Comment: Multiple commenters supported the proposed HEPA but urged CMS to increase the amount of the proposed HEPA multiplier. For example, a commenter expressed their strong support for the proposed HEPA and believed that it is an appropriate incentive to encourage IOTA participants to address barriers that low-income populations face in the transplant process and to help reduce disparities in access to transplant. Furthermore, the commenter felt that the proposed HEPA is also an important tool to ensure IOTA participants are not unfairly penalized if they serve a high number of low-income populations. As such, they recommend that CMS consider increase the health equity performance adjustment.

Additionally, a commenter encouraged CMS to increase the proposed HEPA multiplier to 1.25. Another commenter supported the precision of the IOTA Model's approach, which proposed to apply an adjustor for each individual kidney transplant furnished to a patient meeting the proposed low-income population definition. This individualized method, they argued, would more effectively address health equity compared to the broader approach used in the ETC Model. However, the commenter expressed concerns that the proposed 1.2 multiplier was insufficient to cover the increased costs kidney transplant hospitals would face in expanding transplants for low-income populations. Therefore, the commenter believed it is critical for CMS to consider increasing the multiplier to at least 1.5 in order to incentivize and enable greater transplant access for this underserved group.

Response: We appreciate the commenters' support and recommendations. As described in comment responses noted previously, we will not be finalizing the proposed HEPA. Although we are not finalizing the proposed HEPA at this time, we will take the comment but will consider the appropriate magnitude of any potential adjustment via future rulemaking, as we are not finalizing this provision.

Comment: We received multiple comments supporting the proposed inclusion of a HEPA. For example, several commenters commended CMS's emphasis on and approach to implement a reward only HEPA. They believed the proposed HEPA would be a major stride toward promoting equity in access to organ transplants and motivate IOTA participants to address the barriers faced by low-income individuals in the transplant process. In their comments supporting the proposed HEPA, a couple commenters also expressed gratitude to CMS. They thanked CMS for acknowledging inequities in the transplant process and recognizing that low-income patients may require additional resources to receive a transplant and overcome social barriers to health. These commenters further appreciated CMS for recognizing the extra challenges and burden faced by transplant programs when treating low-income patients, and for its continued efforts to improve service delivery for this population. Lastly, another commenter strongly supported the inclusion of a HEPA, asserting that it serves as an important mechanism to protect IOTA participants from being unduly penalized for serving a high volume of low-income populations.

Response: We appreciate the feedback from commenters. As mentioned in comment responses noted previously in this section, we are not finalizing the proposed HEPA out of the potential for unintended consequences. We plan to monitor the effects of the model on low-income individuals' access to kidney transplants as part of the evaluation process and may consider proposing a new or updated policy through future notice and comment rulemaking, depending on performance by IOTA participants.

Comment: Multiple commenters suggested that CMS only apply the proposed HEPA to living donor transplants. For example, a commenter commended CMS for including the proposed HEPA, noting its structure as a reward-only mechanism. The commenter further suggested that CMS implement a similar ''reward-only'' multiplier based on donor characteristics, which could be integrated into IOTA participants' transplant counts in a similar way. Additionally, the commenter could also envision a multiplier for living donations from historically disadvantaged groups, such as rural and underserved areas. To avoid incentivizing IOTA participants to prioritize deceased donor transplants for low-income candidates out-of-sequence, a commenter suggested that CMS apply the proposed HEPA policy only to living donor transplants.

Response: We thank the commenters for their suggestions. We will not be finalizing the proposed HEPA at this time, 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 address inequities in the transplant process.

Comment: A commenter expressed their appreciation for CMS' focus on low-income patients but noted that these individuals frequently arrive at transplant hospitals with more advanced disease, often due to delayed referrals. Accordingly, the commenter urged CMS to explore alternative models that would facilitate earlier kidney health screenings and improve primary care access for these underserved populations.

Response: We appreciate the commenters' feedback. However, we believe that the IOTA Model works alongside other CMS initiatives aimed at earlier intervention for patients with kidney disease, such as the KCC Model, which focuses on managing care for Medicare beneficiaries with chronic kidney disease and end-stage renal disease.

Comment: Multiple commenters agreed with CMS' decision to not use ADI, pointing out many of the limitations in using ADI to measure inequity in the transplant process. For example, a commenter argued that using the ADI is less optimal than the approach proposed by CMS. The commenter stated that the ADI is a more difficult criterion for transplant hospitals to apply when identifying patients who would qualify for and benefit from interventions. This added complexity would undermine one of the key strengths of the IOTA Model—simplicity. As a result, the commenter

felt that the ADI would be less effective than the clearly defined socioeconomic status (SES) eligibility criteria put forth by CMS in driving behavioral changes at the transplant hospital level. Additionally, the commenter noted that while the ADI is a valuable tool, transplant hospitals typically have a more granular understanding of individual patients' SES, allowing them to easily and immediately identify those who should receive additional support. While another commenter accepted the proposed low-income population definition for this model, recognizing the limitations of the ADI, noting that it fails to adequately capture low-income populations across all regions.

Response: We thank the commenters for their support and do not plan to use the ADI as a way to identify underserved populations in the IOTA Model.

After consideration of public comments received, for the reasons set forth in this rule, CMS is not finalizing the Health Equity Performance Adjustment to the achievement domain, due to the potential for unintended consequences, some of which were pointed out by commenters. We still recognize that there are many inequities in the transplant process and may propose alternative approaches in future notice and comment rulemaking that could address some of the potential consequences laid out by commenters. We also plan to monitor and evaluate the results of the IOTA Model in an effort to see which patients receive transplants in an effort to monitor for any impact of the model based on patient insurance status. However, we are finalizing our proposed methodology for calculating the number of kidney transplants performed during the PY at § 512.424(d) with slight modification. Specifically, since we are not finalizing the proposed health equity performance adjustment at this time, we are modifying our regulation at §§ 512.424(d)(1)(i) and (2) to remove the cross reference to the health equity performance adjustment.

d. Efficiency Domain

At § 512.402 of the proposed rule, we proposed to define the ''efficiency domain'' as the performance assessment category in which CMS assesses the IOTA participant's performance using the organ offer acceptance rate ratio as described in § 512.426. In section III.C.5.d(1) of the proposed rule, we stated that the efficiency domain is focused on improving the overall efficiency of the transplant ecosystem.

In section III.C.5.d(1) of the proposed rule, we proposed including OPTN's organ offer acceptance rate ratio measure in the efficiency domain. The organ offer acceptance rate ratio measure is a ratio of observed organ offer acceptances versus expected organ offer acceptances, as described in section III.C.5.d.(1) of the proposed rule.

(1) Organ Offer Acceptance Rate Ratio

As reviewed in section III.C.5.d(1) of the proposed rule, with over 90,000 unique patients on the waiting list for a kidney transplant, the need to effectively use every available donor organ is critical. However, despite the new allocation system introduced in 2021, and more organs being offered over a wider geographic area, the kidney discard rate has risen to over 24.6 percent and continues to trend upwards.[205] There is a significant shortage of organs available for transplantation, and many patients die waiting for a kidney transplant. Moreover, there are large disparities in organ offer acceptance ratio performance. A 2020 national registry study found that the probability of receiving a deceased donor kidney transplant within three years of placement on the waiting list varied as much as 16-fold amongst different kidney transplant hospitals across the U.S.[206] The study also found that large variations were still present between kidney transplant hospitals that utilized the same OPO and that the probability of transplant was significantly associated with transplant hospitals' offer acceptance rates.[207] By incentivizing kidney organ offer acceptance, we aimed to optimize the use of available organs, thereby reducing underutilization and discards of quality donor organs.

For purposes of assessing the performance of IOTA participants in the achievement domain, we proposed in section III.C.5.d(1) of the proposed rule to include the organ offer acceptance rate ratio as one of the two metrics of performance. We believed that including this measure in the efficiency domain would encourage IOTA participants to increase the utilization of available organs. We also believed that this measure would encourage IOTA participants to improve efficiency in the organ offer process, improve acceptance practices for offers received, and allow for maximal utilization of available organs. We believed that the organ offer acceptance rate ratio is an important system-wide metric, as improved performance by an IOTA participant would also improve opportunities for other kidney transplant hospitals that would not have to wait as long for an available donor kidney. We recognized that all kidney transplant hospitals are already assessed on the organ offer acceptance rate ratio metric under the OPTN, however, we believed that the IOTA Model sets a higher bar for performance, as discussed in section III.C.5.d.(1)(a) of the proposed rule, rather than clearing the threshold that the OPTN sets at 0.30.[208]

As stated in section III.C.5.d(1) of the proposed rule, in the United States, kidney transplant waitlist candidates face considerable disparities in access to kidney transplant, such as in who is referred and placed on the waiting list, who remains ''active'' on the waiting list, and how waitlisted patients are managed by kidney transplant hospitals.[209] Additionally, kidney

[205] MN, 1Scientific R. of T.R., Hennepin Healthcare Research Institute, Minneapolis. (n.d.). *Kidney. Srtr.transplant.hrsa.gov*. Retrieved June 19, 2023, from *https://srtr.transplant.hrsa.gov/annual_reports/2021/Kidney.aspx.*

[206] 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.*

[207] 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.*

[208] *Enhance Transplant Program Performance Monitoring System OPTN Membership and Professional Standards Committee.* (n.d.). *https://optn.transplant.hrsa.gov/media/4777/transplant_program_performance_monitoring_public_comment_aug2021.pdf.*

[209] Schold, J.D., Gregg, J.A., Harman, J.S., Hall, A.G., Patton, P.R., & Meier-Kriesche, H.-U. (2011). Barriers to Evaluation and Wait Listing for Kidney Transplantation. *Clinical Journal of the American Society of Nephrology, 6*(7), 1760–1767. *https://doi.org/10.2215/cjn.08620910;* Hod, T., & Goldfarb-Rumyantzev, A.S. (2014). *The role of disparities and socioeconomic factors in access to kidney transplantation and its outcome. Renal Failure, 36*(8), 1193–1199. *https://doi.org/10.3109/0886022x.2014.934179;* Stolzmann, K.L., Bautista, L.E., Gangnon, R.E., McElroy, J.A., Becker, B.N., & Remington, P.L. (2007). Trends in kidney transplantation rates and disparities. *Journal of the National Medical Association, 99*(8), 923–932. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2574300/;* Paul, S., Melanson, T., Mohan, S., Ross-Driscoll, K., McPherson, L., Lynch, R., Lo, D., Pastan, S.O., & Patzer, R.E. (2021). Kidney transplant program waitlisting rate as a metric to assess transplant access. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 21*(1), 314–321. *https://doi.org/10.1111/ajt.16277;* Cheng, X.S., Busque, S., Lee, J., Discipulo, K., Hartley, C., Tulu, Z., Scandling, J.D., & Tan, J.C. (2018). A new approach to kidney wait-list management in the kidney allocation system era: Pilot implementation and evaluation. *Clinical Transplantation, 32*(11), e13406. *https://doi.org/10.1111/ctr.13406.*

transplant hospital performance is commonly measured by post-transplant outcomes. We recognized that including pre-transplant measures could allow for a more thorough evaluation of transplant hospital performance and provide insight for patient decision-making.

In section III.C.5.d(1) of the proposed rule, we considered several waitlist management metrics for assessing performance in the efficiency domain, such as the number of patients registered to a waitlist, the number or percentage of attributed patients registered on a waitlist with an active waitlist status, or the number or percentage of attributed patients on a waitlist with active waitlist status to inactive waitlist status. Metrics focused on the waitlist could help assess how effectively kidney transplant hospitals are managing their kidney transplant waitlist patients. Organ offers to waitlist kidney transplant patients are made directly to the kidney transplant hospital where they are waitlisted. Once a kidney transplant hospital receives an organ offer for one of their kidney transplant waitlist patients, it is ultimately its decision to accept or decline an organ offer on the patient's behalf. Kidney transplant hospitals are not required to inform kidney transplant waitlist patients for whom an offer was received when an organ offer was received or why an organ offer was declined. While we understood the importance of a transplant surgeon's clinical decision-making and respected the clinical judgement of transplant surgeons, declining an offer without involving the affected patient in the decision-making can be detrimental to the patient, as additional time on the waitlist can negatively impact the patient's quality of life.[210]

As stated in section III.C.5.d(1) of the proposed rule, we also considered including a waitlist mortality metric for assessing efficiency domain performance, so as to incentivize improvements in mortality outcomes of attributed patients on a waitlist. On average, as many as 20 patients on the waitlist for a kidney transplant die each day waiting for a kidney transplant in the United States.[211] While a waitlist mortality metric may help assess patient outcomes and experience while waiting for an organ offer,[212] and provide insight into differences in waitlist management practices across kidney transplant hospitals, we recognize that waitlist mortality rate is also influenced by the insufficient supply of donor organs available for transplantation. We also recognized that IOTA participants may not have a direct effect on, or ability to improve, mortality metrics, as nephrologists are also closer to the direct care of waitlist patients and would have a greater ability to affect their care and mortality rate. Furthermore, we believed that we are already testing the ability of nephrologists to manage care for Medicare beneficiaries with ESRD or CKD via the KCC Model.

We also considered several other metrics for assessing efficiency domain performance related to time to transplant, as outlined in section III.C.5.d(1) of the proposed rule, such as—

- Time from initial evaluation to transplant;
- Time from initial referral to transplant;
- Time from initial placement on a waitlist to transplant; and
- Time from when a patient was initially referred to time of initial evaluation to time of initial placement on a waitlist to time to transplant.

As discussed in section III.C.5.d(1) of the proposed rule, before a patient can be considered for, and placed on, the waiting list for a kidney transplant, they must first be referred by either a nephrologist or dialysis facility, at which point they undergo a comprehensive evaluation process by a transplant hospital.[213] Studies have shown long-standing barriers and disparities to access to transplantation by patient demographics, such as racial/ethnic, sex, socioeconomic, and insurance factors.[214] Disparities are driven by various factors, but we recognized that delays or lack of referrals for evaluation, evaluation criteria that may unintentionally deem a patient not eligible to be placed on a waitlist, and organ acceptance rate variations across kidney transplant hospitals, may exacerbate disparities. Thus, measuring time to transplant was considered an appropriate potential performance metric that could incentivize IOTA participants to improve. However, we chose not to propose this type of measure due to concerns about how to properly measure start and end points and unintended consequences that may harm patients, as it may create opportunities for kidney transplant hospitals to manipulate average times by only adding patients to the waitlist when they are certain of imminent transplant, which could exacerbate waitlist inequities.

We also considered including a transplantation referral to evaluation conversion rate measure, as discussed in section III.C.5.d(1) of the proposed rule. For patients with ESRD, access to transplantation is influenced by both referral patterns of pre-transplantation providers and transplant hospital processes of care and evaluation criteria.[215] Additionally, some studies found considerable variation in referral rates to transplantation by dialysis facilities, proposing significant regional and facility-level variation in care.[216]

[210] Husain, S.A., King, K L., Pastan, S., Patzer, R.E., Cohen, D.J., Radhakrishnan, J., & Mohan, S. (2019). Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Network Open, 2*(8), e1910312. *https://doi.org/10.1001/jamanetworkopen.2019.10312.*

[211] Delmonico, F.L., & McBride, M.A. (2008). Analysis of the Wait List and Deaths Among Candidates Waiting for a Kidney Transplant. *Transplantation, 86*(12), 1678–1683. *https://doi.org/10.1097/tp.0b013e31818fe694.*

[212] Shepherd, S., & Formica, R.N. (2021). *Improving Transplant Program Performance Monitoring. 8*(4), 293–300. *https://doi.org/10.1007/s40472-021-00344-z;* Wey, A., Gustafson, S.K., Salkowski, N., Kasiske, B.L., Skeans, M., Schaffhausen, C.R., Israni, A.K., & Snyder, J.J. (2019). *Association of pretransplant and posttransplant program ratings with candidate mortality after listing. 19*(2), 399–406. *https://doi.org/10.1111/ajt.15032.*

[213] Paul, S., Plantinga, L.C., Pastan, S.O., Gander, J.C., Mohan, S., & Patzer, R.E. (2018). Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities. *Clinical Journal of the American Society of Nephrology, 13*(2), 282–289. *https://doi.org/10.2215/cjn.04690417;* Redeker, S., Massey, E.K., van Merweland, R.G., Weimar, W., Ismail, S.Y., & Busschbach, J.J.V. (2022). Induced demand in kidney replacement therapy. *Health Policy, 126*(10), 1062–1068. *https://doi.org/10.1016/j.healthpol.2022.07.011;* Knight, R.J., Teeter, L.D., Graviss, E.A., Patel, S.J., DeVos, J.M., Moore, L.W., & Gaber, A.O. (2015). Barriers to Preemptive Renal Transplantation. *Transplantation, 99*(3), 576–579. *https://doi.org/10.1097/tp.0000000000000357;* Schold, J.D., Patzer, R.E., Pruett, T.L., & Mohan, S. (2019). Quality Metrics in Kidney Transplantation: Current Landscape, Trials and Tribulations, Lessons Learned, and a Call for Reform. *American Journal of Kidney Diseases, 74*(3), 382–389. *https://doi.org/10.1053/j.ajkd.2019.02.020.*

[214] Shepherd, S., & Formica, R.N. (2021). *Improving Transplant Program Performance Monitoring. 8*(4), 293–300. *https://doi.org/10.1007/s40472-021-00344-z;* Ernst, Z., Wilson, A., Peña, A., Love, M., Moore, T., & Vassar, M. (2023). Factors associated with health inequities in access to kidney transplantation in the USA: A scoping review. *Transplantation Reviews,* 100751. *https://doi.org/10.1016/j.trre.2023.100751.*

[215] Schold, J.D., Patzer, R.E., Pruett, T.L., & Mohan, S. (2019). Quality Metrics in Kidney Transplantation: Current Landscape, Trials and Tribulations, Lessons Learned, and a Call for Reform. *American Journal of Kidney Diseases, 74*(3), 382–389. *https://doi.org/10.1053/j.ajkd.2019.02.020.*

[216] Ibid; Alexander, G. Caleb., & Sehgal, A.R. (2002). Variation in access to kidney transplantation across dialysis facilities: Using process of care measures for quality improvement. *American Journal of Kidney Diseases, 40*(4), 824–831. *https://doi.org/10.1053/ajkd.2002.35695;* Patzer, R.E., Plantinga, L.C., Paul, S., Gander, J., Krisher, J., Sauls, L., Gibney, E.M., Mulloy, L., & Pastan, S.O. (2015). Variation in Dialysis Facility Referral for

However, because dialysis facilities are often the primary referrer and are not IOTA participants, we did not propose this measure. We also had concerns about how this data would be collected.

Finally, we also considered a living donor rate as one of the metrics used to assess performance in the efficiency domain to measure percentage of potential living donors who are evaluated to donate a kidney and that actually donated a kidney. This metric could help assess success towards addressing living donor concerns and improvements in education on the living donor process. However, we did not propose this metric because we have concerns about our ability to access data needed for measurement.

Ultimately, as discussed in section III.C.5.d(1) of the proposed rule, we chose not to propose to include waitlist management metrics when assessing IOTA participant performance in the efficiency domain because we believed that waitlist costs are already accounted for in the Medicare cost report. Transplant waitlist measures also do not capture living donation, which is an additional path to a successful kidney transplant that CMS already incentivizes living donations in the ETC Model. Moreover, studies have shown that organ acquisition costs have been rising and were not solely attributable to the cost of procurement, suggesting that an increased focus on the waiting list could further increase Medicare expenditures.[217] Also, for some of the measures considered (that is, waitlist mortality, transplantation referral to evaluation rate), nephrologists and dialysis facilities play large roles in maintaining the patient's health, and we did not believe it is appropriate to include a measure that would depend largely upon the behavior and actions of physicians and facilities other than the IOTA participant. We also thought this type of measure could distract from increasing rates of transplant and provide false expectations for time to transplant for kidney transplant waitlist patients. We are also concerned that a waitlist measure could have unintended consequences and potentially lead to those most in need of transplant not being listed to receive a transplant.

We solicited comment on our proposed organ offer acceptance rate ratio metric for purposes of assessing performance in the efficiency domain, and the alternatives considered.

The following is a summary of the comments received on our proposed use of the organ offer acceptance rate ratio in the efficiency domain and our responses:

Comment: A commenter was specifically opposed to including the OPTN organ offer acceptance rate measure in the efficiency domain. A few other commenters were concerned with using the organ offer acceptance rate ratio because it may be inflated by a high use of out-of-sequence kidneys, or it may promote kidney transplant hospitals to perform more DDKTs.

Response: We thank the commenters for their feedback. While there is no downside risk for out-of-sequence allocation we acknowledge commenters' concerns that an unintended consequence of using the organ offer acceptance rate ratio performance metric could be a rise in out-of-sequence allocation. We encourage the transplant community to continue providing feedback about appropriately capturing out-of-sequence organ offers, as we will consider this for future rulemaking and performance years. While we agree with the commenter who stated that the organ offer acceptance rate ratio metric may increase DDKTs, we do not believe that this automatically means that transplants will be of lesser quality. There are currently underutilized subsets of deceased donor kidneys and high rates of organ non-use [218] due to a number of reasons including, but not limited to, systematic inefficiencies [219] and lack of organ filters.[220] We refer readers to sections III.B and III.C.5.d(1) of this final rule for further discussion on organ acceptance patterns. Pre-existing OPTN mortality metrics and the new composite graft survival metric that we mention in section III.C.5.e of this final rule discourage transplant programs from transplanting kidneys that are very obviously not viable.

Comment: A few commenters suggested that if CMS is using the organ offer acceptance rate ratio measure, that they need to address out-of-sequence allocation, should utilize SRTRs risk adjustment, and should modify OPTN codes to develop more targeted responses to the discard rate.

Response: We thank the commenters for their suggestions. As previously mentioned in comment responses in this section, while there is no downside risk for out-of-sequence allocation in the IOTA Model, we acknowledge commenters concern that an unintended consequence of using the organ offer acceptance rate ratio performance could be an increase in out-of-sequence allocation. We encourage the transplant community to continue providing feedback about appropriately capturing out-of-sequence organ offers, as we will consider this for future rulemaking and performance years.

We intend to use the SRTR risk adjustment model for the offer acceptance metric; see section III.C.5.e of this final rule for more details.

Comment: A commenter stated that offers should be analyzed via validated metrics.

Response: We thank the commenter for their response. The organ offer acceptance rate ratio has been utilized by SRTR since 2023 and while lacking formal validation, is not unknown to the transplant community.[221] With the use of this measure by SRTR and CMS by way of the IOTA Model, we believe this creates opportunity to better understand its validity and adapt risk-adjustment.

Comment: A commenter requested clarification around what is considered an ''unsuitable kidney'' in the list of exclusions for the expected organ offer acceptance.

Response: We recommend the commenter review Table 6 in section III.C.5.d(1)(a) of this final rule, for a full list of exclusions from the measure. While an ''unsuitable kidney'' is not specifically listed in the exclusion list, we believe that the exclusion criteria of a kidney having a ''match run with no acceptances'' would apply.

Comment: A commenter was concerned that the organ offer acceptance metric was too broad and should be calculated based on offers within and outside of a 250-mile radius given the variation in regional importing of organs and the variation in kidney transplant hospital wait times.

Response: We appreciate the commenter's feedback. This was not a

Kidney Transplantation Among Patients With End-Stage Renal Disease in Georgia. *JAMA, 314*(6), 582. *https://doi.org/10.1001/jama.2015.8897.*

[217] Cheng, X.S., Han, J., Braggs-Gresham, J.L., Held, P.J., Busque, S., Roberts, J.P., Tan, J.C., Scandling, J.D., Chertow, G.M., & Dor, A. (2022). Trends in Cost Attributable to Kidney Transplantation Evaluation and Waitlist Management in the United States, 2012–2017. *JAMA Network Open, 5*(3), e221847. *https://doi.org/10.1001/jamanetworkopen.2022.1847.*

[218] Mohan, S., Yu, M., King, K.L, & Husain, S.A. (2023) Increasing discards as an unintended consequence of recent changes in United States kidney allocation policy. *Kidney International Reports,* 8(5): 1109–1111. *https://doi.org/10.1016/j.ekir.2023.02.108.*

[219] Wood, N.L., VanDerwerken, D.N., Segev, D.L., & Gentry, SE (2022). Increased logistical burden in circle-based kidney allocation. *Transplantation,* 106(10): 1885–1887. *https://doi.org/10.1097/tp.0000000000004127.*

[220] UNOS. (2023, September 5). Research in focus: Examining organ offers. Retrieved October 11, 2024 from *https://unos.org/news/in-focus/organ-offers/#Impact.*

[221] OPTN. (2023, September 14). New pre-transplant performance metric now in effect, offer acceptance rate ratio. Retrieved August 15, 2024 from *https://optn.transplant.hrsa.gov/news/new-pre-transplant-performance-metric-now-in-effect-offer-acceptance-rate-ratio/.*

consideration made during proposed rulemaking in order to align our metric with the pre-existing SRTR methodology. We are, however, interested in considering this for future rulemaking.

Comment: Many commenters stated their support for the use of OPTN's organ offer acceptance rate measure in the efficiency domain.

Response: We thank the commenters for their support.

Comment: A commenter conveyed concern that listing practices could penalize them in the efficiency domain. For example, if a transplant program listed all patients for high KDPI kidneys, resulting in passing on kidneys for offers sometimes, their organ offer acceptance rate ratio could be impacted.

Response: We appreciate the commenter's feedback. While IOTA participants may choose to encourage all their patients to enroll for kidneys with a KDPI greater than 85 to increase their offer opportunity, as the commenter points out, this may have risks. The purpose of selecting organ offer acceptance rate ratio as a metric is to increase utilization of available organs. If frequent ''passing'' is occurring for patients listed for kidneys with a KDPI greater than 85, there may be additional opportunities for utilizing filters. We also acknowledge that no transplant program will accept every offer they receive due to outliers and offers that may not be ideal due to comorbidities/risks of the donor kidney and recipient or both. Results in PY 1 will be monitored closely, to help identify reasonable and achievable organ offer acceptance ratio goals for future performance years and rulemaking.

Comment: A commenter was concerned that organ offer acceptance rate metric will encourage more conservative choices, which contradicts increasing overall kidney transplant volume, another goal of the IOTA Model.

Response: We appreciate your feedback; however, we believe the three performance domains counterbalance each other. The three performance domains challenge IOTA participants to consider if there is opportunity for growth in their kidney transplant hospital and how to navigate the task of increasing volume while offering a good quality of life for patients and appropriate long-term outcomes while minimizing non utilization of organs when possible. We would argue that the organ offer acceptance rate ratio measure does not encourage conservative choices but rather choices that better align with organs they will accept, to prevent overall organ non-use. We are asking IOTA participants to consider fine-tuning their organ offer filters and general processes.

Comment: A commenter suggested that the performance measures include a metric assessing performance in excluded communities, awarding IOTA participants more points who have organ offer acceptance rate ratios matching population needs and showing evidence of improved access to underserved populations. Similarly, a commenter suggested stratifying organ offer acceptance rate ratios by the beneficiary's payer, race, ethnicity and the income of the local population.

Response: Thank you for your responses. We did not consider further stratifying organ offer acceptance rate ratio goals. This approach could aid in identifying disparities across kidney transplant waitlist patients and organ offer acceptance patterns; however, it may be challenging to create adjusted metrics specific to each IOTA participant and their local population needs. This would also require IOTA participants to annually identify their local population to formulate baselines. These calculations would then need to be utilized to determine how to award points to IOTA participants who exceed expectations for underserved populations. We are interested in considering how the organ offer acceptance rate ratio could be tailored to local populations and underserved communities during future rulemaking.

Comment: A couple of commenters suggested CMS use a living donor metric. They had specific concerns that a domain dependent on DDKTs may not help to increase LDKTs. A commenter stated that CMS should include a living donor metric such as converting potential to actual living donors, and another stated CMS should implement a living donor and pre-emptive transplant measure given the significant benefits with living donation.

Response: We thank the commenters for their suggestions. We intend to further consider how living donor metrics could be included in future rulemaking. Setting a target number for the number of living donor evaluations versus the actual number of living donor evaluations who proceed with a surgery creates numerous risks. This could inadvertently cause kidney transplant hospitals to change their practices for those patients they accept for evaluations (potentially lowering criteria thresholds) or who they approve to be donors. Either result could cause reduced access to donation and create ethical concerns or both. While we do not believe that this would be an appropriate metric for the IOTA Model, we do however, encourage ongoing feedback about other opportunities for metrics specific to living donation.

Comment: A commenter requested use of a measure that does not incentivize acceptance of organ offers for the sole purpose of reaching a target number.

Response: We appreciate the commenter's feedback. We acknowledge that almost all metrics are imperfect. The purpose of including organ offer acceptance rate as a metric is to increase utilization of available organs in the system. The efficiency domain, as proposed, is not dependent on volume of kidney transplants performed but how well kidney transplant hospitals can prevent receiving offers they will knowingly decline, how kidney transplant hospitals can optimize filters to meet their individual needs and minimize organ non-use. We believe that performing well in the efficiency domain will result in more efficient utilization of organs, which can impact the number of organs transplanted.

Comment: A commenter recommended following adjusted non-use rates to account for different donor pools year-to-year.

Response: We appreciate the commenter's response. In the context of organ offer acceptance rate ratio, as described and finalized in III.C.5.d (1)(a) of this final rule, we are utilizing a risk adjustment model from year-to-year to account for consistent measurement between PYs.

Comment: A commenter suggested adding a metric that specifically follows non-utilization, particularly for kidneys with a KDPI greater than 85.

Response: We thank the commenter for their suggestion. While kidneys with a KDPI greater than 85 have high non-use rates, we recognize that there is underutilization of kidneys in all categories. Furthermore, in PY 1 we believe it is ideal to improve utilization broadly, which allows IOTA participants the flexibility to focus on improving access to groups of donors and recipients that may vary between regions and IOTA participants.

Comment: A commenter suggested routine reviews of the organ offer acceptance rate ratio metric to guarantee high quality outcomes.

Response: We thank the commenter for their feedback and agree that the organ offer acceptance rate ratio calculations and goals will need to be monitored closely to ensure their use improves the performance of IOTA participants without unintended consequences. If analysis results warrant a new or updated policy, we

will address it pursuant to future rulemaking.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing, as proposed, our provisions to assess performance in the efficiency domain using the organ offer acceptance rate ratio metric at §§ 512.426(a) and (b), as described and finalized in section III.C.5.d(1) of this final rule. We direct readers to section III.C.5.d(1)(a) of this final rule for a full discussion on the organ offer acceptance rate ratio methodology. As described and finalized in section III.C.5.d(1)(c) of this final rule, we are finalizing the proposed provisions for the point allocation and calculation methodology for the efficiency domain scoring and scoring for organ offer acceptance rate ratio for the IOTA Model at § 512.426(c), with slight modifications. We direct readers to section III.C.5.d.(1).(b). of this final rule for a full discussion on the point allocation and calculation methodology for the organ offer acceptance rate ratio metric.

We are also codifying at § 512.402 the definition of efficiency domain as the performance assessment category in which CMS assesses the IOTA participant's performance using the organ offer acceptance rate ratio as described in § 512.426. We intend to analyze and monitor IOTA participant performance to ensure we do not unduly disadvantage IOTA participants selected for the IOTA Model. If analysis warrants a new or updated policy, we will address it pursuant to future rulemaking.

(a) Calculation of Metric

In section III.C.5.d(1)(a) of the proposed rule, we proposed calculating organ offer acceptance rates for an IOTA participant using OPTN's offer acceptance rate ratio performance metric (see Equation 1). Per OPTN's new offer acceptance rate ratio, a rate ratio for a kidney transplant hospital that is greater than 1 indicates that the kidney transplant hospital usually accepts more offers than expected. A rate ratio that is less than 1 conveys a kidney transplant hospital's tendency to accept fewer offers than expected compared to national offer acceptance practices.[222] The OPTN MPSC has reported that this metric assesses kidney transplant hospitals' rate of observed organ offer acceptances to expected acceptances and is intended to answer the following question: Given the types of offers received to the specific candidates, does this program accept offers at a rate higher/lower than national experience for similar offers to similar candidates.[223]

Equation 1: Organ Offer Acceptance Rate Ratio [224]

$$Organ\ Offer\ Acceptance\ Rate\ Ratio\ = \frac{Number\ of\ Acceptances\ +\ 2}{Number\ of\ Expected\ Acceptances\ +\ 2}$$

As discussed in section III.C.5.d(1)(a) of the proposed rule, expected acceptances are based solely on kidneys that are accepted and transplanted by a kidney transplant hospital, so unsuitable kidneys are excluded from this measure, and are calculated using logistic regression models to determine the probability that a given organ offer will be accepted. The measure, as specified by SRTR methodology, is inherently risk adjusted as it only counts organs that are ultimately accepted by a kidney transplant hospital.[225] We proposed to use SRTR data to calculate the OPTN organ offer acceptance rate ratio, as described in section III.C.5.d.(1)(a) of the proposed rule.

Per the SRTR measure, we proposed in section III.C.5.d(1)(a) of the proposed rule, dividing the number of kidney transplant organs accepted by each IOTA participant (numerator) by the risk-adjusted number of expected organ offer acceptances (denominator).[226] This measure utilizes a logistic regression and risk adjusts for the following: donor quality and recipient characteristics; donor-candidate interactions, such as size and age differences; number of previous offers; and, distance of potential recipient from the donor.[227] We proposed to use SRTR's adult kidney model strata risk adjustment methodology and most recently available set of coefficients to calculate the number of expected organ offer acceptances.

For example, suppose we have a model for predicting the probability a kidney offer will be accepted, and this model adjusts for the number of years the candidate has been on dialysis, whether the kidney was biopsied, and the distance between the donor hospital and the candidate's transplant center (89 FR 43557). Consider the offer of a biopsied kidney 150 nautical miles (NM) away to a candidate who has been on dialysis for 2 years. As described in section III.C.5.d(1)(a) of the proposed rule, to calculate the probability of acceptance, we would first multiply these values by their respective model coefficients and then sum up those products with the model's intercept, as illustrated in Table 5.[228]

[222] OPTN. (2022). *OPTN Enhanced Transplant Program Performance Metrics. https://optn.transplant.hrsa.gov/media/r5lmmgcl/mpsc_performancemetrics_3242022b.pdf.*

[223] *Mpsc-enhance-transplant-program-performance-monitoring-system_srtr-metrics.pdf.* (n.d.). Retrieved December 28, 2022, from *https://optn.transplant.hrsa.gov/media/qfuj3osi/mpsc-enhance-transplant-program-performance-monitoring-system_srtr-metrics.pdf.*

[224] Ibid.

[225] Scientific Registry of Transplant Recipients. (n.d.). *Risk Adjustment Model: Offer Acceptance.* Offer acceptance. *https://www.srtr.org/tools/offer-acceptance/.*

[226] Ibid.

[227] SRTR. (2023). Srtr.org. *https://tools.srtr.org/OAModelApp_2205/;* Ibid.

[228] CMS notes that some risk adjustment factors in the SRTR models may only apply in certain ranges of a continuous variable. For example, a term that applies if the patient's age at the time of listing is >35 may be named ''can_age_at_listing_right_spline_knot_35''. In these cases, obtain the product using this formula if the patient's age at listing was >35: product = (Age − 35)*(model coefficient). Others may apply if the value is less than (<) a specified value. For example, for a term like ''can_age_at_listing_left_spline_knot_18'', obtain the product for a patient younger than 18 as: product = (18 − Age)*(model coefficient).

TABLE 5: EXAMPLE OF SUMMING UP COEFFICIENTS

Risk Adjustment Factor	Value	Coefficient	Product
Kidney Biopsied	Yes (use 1 for yes)	-1.750	-1.750
Years on Dialysis	2	0.250	0.500
Distance (NM)	150	-0.0035	-0.525
Intercept	(use 1 for intercept)	-0.255	-0.225
Total			-2

We would then plug that total into the following equation (see Equation 2) to get that the probability of acceptance is approximately 0.119 (that is., 11.9 percent chance of acceptance).

Equation 2: Probability of Organ Offer Acceptance

$$Probability\ of\ Organ\ Offer\ Acceptance\ = \frac{e^{-2}}{1+e^{-2}}$$

To determine the number of offers a transplant program was expected to accept, we would add up the probability of acceptance for every offer that transplant program received (89 FR 43557). The final organ offer acceptance rate ratio (OAR) is then constructed from the observed (O) number of acceptances and the expected (E) number of acceptances using Equation 1 as described in section III.C.5.d(1)(a) of this final rule. In this example we showed a simple logistic regression model that only included three risk-adjusters. The actual models used by the SRTR adjust for many more variables, but the process demonstrated here is the same.

As discussed in section III.C.5.d(1)(a) of the proposed rule, a kidney may be transplanted into a candidate who did not appear on the match run, usually to avoid discard if the intended recipient is unable to undergo transplant. If the eventual recipient was not a multi-organ transplant candidate and was blood type compatible per kidney allocation policy, then these transplants would be included in the organ offer acceptance rate. For purposes of the IOTA Model, we proposed to define ''match run'' as a computerized ranking of transplant candidates based upon donor and candidate medical compatibility and criteria defined in OPTN policies.

Per OPTN's new organ offer acceptance rate ratio, as described in section III.C.5.d(1)(a) of the proposed rule, Table 6 summarizes the types of organ offers that we proposed be included and excluded in the calculation of this metric. For the purposes of organ offers excluded from the organ offer acceptance rate ratio, we proposed to define ''missing responses'' as organ offers that the kidney transplant hospital received from the OPO but did not submit a response (accepting or rejecting) in the allotted time frame from the time the offer was made per OPTN policy 5.6.B.[229] For purposes of organ offers excluded from the organ offer acceptance rate ratio measure, we proposed to define ''bypassed response'' as an organ offer not received due to expedited placement [230] or a decision by a kidney transplant hospital to have all of its waitlisted candidates skipped during the organ allocation process based on a set of pre-defined filters matching the characteristics of the potential organ to be transplanted.[231]

[229] OPTN. (2023). *OPTN Policies. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

[230] Expedited placement has the potential to minimize delays in organ allocation by directing organs that may not be ideal to transplant centers that have demonstrated a willingness to utilize such organs. Currently, expedited placement, also known as ''accelerated placement'' or ''out-of-sequence'' allocation, permits OPOs to deviate from the standard match run, which determines the priority of patients on the waiting list for organ offers, under exceptional circumstances. This discretionary tool of expedited placement is employed by OPOs when there are suboptimal donor characteristics associated with donor disease or recovery-related issues, in order to prevent the organ from going unused. For numerous years, expedited organ placement has played a crucial role in organ allocation, enabling OPOs to promptly allocate organs that they believe are at risk of not being utilized for transplantation.

[231] King, K.L., S Ali Husain, Cohen, D.J., Schold, J.D., & Mohan, S. (2022). The role of bypass filters in deceased donor kidney allocation in the United States. *American Journal of Transplantation, 22*(6), 1593–1602. *https://doi.org/10.1111/ajt.16967; Transplant Quality Corner | The New MPSC Metric.* (n.d.). The Organ Donation and Transplantation Alliance. Retrieved February 23, 2024, from *https://www.organdonationalliance.org/insights/quality-corner/new-mpsc-metric/.*

TABLE 6: ORGAN OFFERS INCLUDED AND EXCLUDED FROM MEASURE[232]

Offers Included in Measure	Offers Excluded from Measure
• Organ offers that are ultimately accepted and transplanted. • Offers to candidates on a single organ waitlist (except for Kidney/Pancreas candidates that are also listed for kidney alone).	• Multiple match runs from same donor combined and duplicate offers. • Match run had no acceptances. • Offer occurred after last acceptance in a match run. • Missing or bypassed response. • Offers to multi-organ candidates (except for Kidney/Pancreas candidates that are also listed for kidney alone).

As discussed in section III.C.5.d(1)(a) of the proposed rule, we believed that IOTA participants could improve on the organ offer acceptance rate ratio metric in at least two ways. First, IOTA participants could increase the number of organ offers they accept, which would also potentially lead to greater performance scores in the achievement domain. Second, IOTA participants could also decrease the number of expected acceptances by adding better filters so that they are only receiving offers that they are likely to accept. Stricter filters may help ensure that an IOTA participant is not delaying the allocation of organs that they are uninterested in that could otherwise be accepted by another kidney transplant hospital. Since there are multiple ways to improve the offer acceptance ratio, the IOTA Model is not requiring increased utilization of higher KDPI kidneys that some IOTA participants may not want to use due to their clinical protocols. Additionally, the IOTA Model is not prescribing or requiring specific care delivery transformation or improvement activities of IOTA participants, so as to allow for flexibility and innovation.

In section III.C.5.d(1)(a) of the proposed rule, we considered calculating the organ offer acceptance rate by dividing the number of organs each IOTA participant accepts by the number offered to that transplant hospital's patients that are ultimately accepted elsewhere; however, the lack of risk adjustment in this metric may be unfair to some IOTA participants (89 FR 43558).

As mentioned in section III.C.5.d(1)(a) of the proposed rule, we also considered updating the calculation for organ offer acceptance rate ratio to account for the benefits of living donation by increasing the number of organs in the system because the proposed organ offer acceptance rate ratio only shows improvement in deceased donor utilization. This modification would add a single 1 in the numerator and a single 1 in the denominator for each living donation a transplant hospital completes. However, we did not propose updating the organ offer acceptance rate ratio because we decided to focus on deceased donor acceptance to remain aligned with the SRTR calculation. We also did not believe this was appropriate to propose because we believe that IOTA participants with an established or high performing living donation program would be able to gain points more easily in the achievement domain, which has a larger percent of overall points, which we thought may be unfair to IOTA participants that do not.

We sought comment on our proposal to use and calculate the OPTN organ offer acceptance rate ratio in accordance with OPTN's measure specifications and SRTR's methodology as the metrics that would determine IOTA participants' performance on the efficiency domain. We also sought comments on the alternatives we considered. Additionally, we sought comment on our proposed definitions.

The following is a summary of the comments received on our proposed utilization of the organ offer acceptance rate ratio using OPTN measure specifications and SRTR metrics for the efficiency domain and our responses:

Comment: Several commenters requested clarification for how organ offer filters will be used when calculating the organ offer acceptance rate ratio. They were concerned that using filters may create conflicts between kidney transplant volume and offer acceptances.

Response: We appreciate the commenters' feedback. Organ offer filters allow kidney transplant hospitals to specify characteristics of donors or donor-recipient matches they would not transplant at their transplant program, to prevent unnecessary organ offers and to allow the organ to go to another kidney transplant hospital who may accept the offer, more expeditiously. Organ filter use does not directly contribute to the organ offer acceptance rate ratio calculation. Use of filters, however, can impact the calculation result. Kidney transplant hospitals may choose to use less filters, allowing increased offers; or they may choose to use more strict filters to ensure that they are very likely to accept the offers they receive. We acknowledge that kidney transplant hospitals will not accept every organ offer and that they must maintain some flexibility to keep some filter criteria liberal to meet the needs of some of their beneficiaries, however, we believe these practices will be relatively consistent between kidney transplant hospitals to create comparable results. We also agree that it may take kidney transplant hospitals time to optimize their organ offer filters and their increase in kidney transplants, which is one of the reasons that we ensured that PY 1 does not have any downside risk, regardless of final performance score.

Comment: A few commenters requested clarification as to whether CMS would create a new organ acceptance rate measure, stating it must be validated, if so.

[232] OPTN. (2022). *OPTN Enhanced Transplant Program Performance Metrics. https://optn.transplant.hrsa.gov/media/r5lmmgcl/mpsc_performancemetrics_3242022b.pdf; For Transplant Center Professionals.* (n.d.). *www.srtr.org.* Retrieved February 22, 2023, from *https://www.srtr.org/faqs/for-transplant-center-professionals/#oaconsideration.*

Response: As outlined in section III.C.5.d(1)(a) of this final rule, we proposed OPTN's measure specifications and SRTR's methodology.

Comment: Several commenters stated their concerns about the CMS calculations for organ offer acceptance rate ratio. Each commenter within this group had a different concern, including the lack of risk adjustment, unfair comparison of large and small kidney transplant hospitals, how calculations are applied to beneficiaries that are toward the bottom of the waitlist and if the methodology will make a kidney transplant hospital's waitlist criteria more strict.

Response: We thank the commenters for their feedback. The SRTR methodology outlined in section III.C.5.d.(1).(a). of this final rule includes a risk-adjusted number of expected organ offer acceptances in its calculation.

While we acknowledge the different challenges of IOTA participants with variable volumes of kidney transplants, we also believe that each category of IOTA participants has different opportunities to impact their organ offer acceptance rate ratio. An IOTA participant with high volume of kidney transplants may focus on accepting higher score kidneys, whereas an IOTA participant with low volume of kidney transplants may be able to have more strict filter criteria to ensure the organ offers they receive are those that they will accept.

The SRTR methodology is based on a match run, if the IOTA participant accepts an organ offer and whether the IOTA participant was expected to accept the offer, based on the methodology and risk adjustment as described in section III.C.5.d.(1).(a). of this final rule. If a kidney transplant waitlist patient is not at the top of the waiting list and does not match, this calculation would not be applicable.

Finally, we agree that if a kidney transplant hospital uses very strict filter criteria this could impact their waitlist, however, we also believe it is important to consider having organ offer filter criteria reflect the organ offers that their transplant programs actually accept. The organ offer acceptance rate ratio methodology and subsequent use of organ offer filters encourages IOTA participants to minimize non-use of organs and minimize cold ischemic times.

Comment: A commenter requested clarification around what is considered an ''unsuitable kidney'' in the list of exclusions for the expected organ offer acceptance rate ratio.

Response: We recommend the commenter review III.C.5.d.(1)(a) Table 6 for a full list of exclusions from the measure. If a kidney transplant organ is not used by any kidney transplant hospital, that kidney is excluded from the organ offer acceptance rate ratio calculation.

Comment: A commenter stated they agreed with the inclusion and exclusion criteria for organ offers included in the calculation of the organ offer acceptance rate ratio.

Response: We thank the commenter for their support.

Comment: A commenter was concerned that out-of-sequence kidney offers are included in the measurement of success. Similarly, another commenter suggested CMS monitor the rate of out-of-sequence allocation that occurs.

Response: We appreciate the commenter's feedback. The commenter is correct that the SRTR methodology does not account for out-of-sequence kidney offers. Given the historic rise of out-of-sequence allocation over the last few years, we intend to monitor this closely.[233] If analysis results warrant a new or updated policy, we will address it pursuant to future rulemaking.

Comment: A commenter asked that CMS clarify filter use and how it would impact those patients that remain after filtering.

Response: We appreciate the commenter's feedback. Organ offer filters allow kidney transplant hospitals to specify characteristics of donors or donor-recipient matches they would not transplant at their transplant program, to prevent unnecessary organ offers and to allow the organ to go to another kidney transplant hospital who may accept the offer, more expeditiously. By utilizing filters that more closely match what offers a kidney transplant hospital is likely to accept for their waitlisted patients, the kidney transplant hospital will have a higher likelihood of organ offer acceptance. Furthermore, this would increase their organ offer acceptance rate ratio.

Comment: A commenter was concerned that the SRTR methodology does not account for non-viable kidneys.

Response: We appreciate the commenters concern and agree that not all offers are viable and acknowledges this in section III.C.5.d.(1).(a). of this final rule, Table 6, where exclusions for the organ offer acceptance rate ratio metric are included. Kidney match runs that have no acceptances are excluded in this metric. The calculation leaves ''viability'' judgment to the kidney transplant hospitals. If the commenter is concerned that there are too many non-viable kidney organ offers occurring, this would be a matter that may need to be discussed with OPOs and is outside the scope of the IOTA Model.

Comment: A commenter disagreed with use of the SRTR data because the c-statistic of their tool has not been published.

Response: We thank the commenter for their feedback. Availability of the published c-statistic of the SRTR data is not something we took into consideration, however, we believe that the SRTR methodology and OPTN data is appropriate for use in the IOTA Model given its risk adjustment, as outlined in section III.C.5.d.(1).(a). of this final rule. If analysis results warrant a new or updated policy, we will address it pursuant to future rulemaking.

Comment: A commenter suggested CMS modify its organ offer acceptance rate ratio calculation methodology by dividing accepted organs by organs offered elsewhere that are accepted.

Response: We thank the commenter for their suggestion. We previously considered this as an option for the efficiency domain performance metric; however, we were concerned that the lack of risk adjustment would be unfair to IOTA participants.

Comment: A few commenters suggested that CMS not use the SRTR methodology. Each individual commenter had a different concern, including that this methodology follows unproven outcomes, that the UNOS data is more up to date than SRTR data, and that using SRTR methodology conflicts with the achievement domain.

Response: We appreciate the commenters' suggestions and concerns and hope to provide some clarification. We are not using SRTR data and note that there is not ''UNOS data''. The SRTR methodology is calculated with OPTN data. By using the same methodology and data as the OPTN's organ offer acceptance rate ratio metric, the IOTA Model results will align with those tested by OPTN/UNOS, as recommended by the MPSC. As previously mentioned, the organ offer acceptance rate ratio has been utilized by SRTR since 2023 and while lacking formal validation, is not unknown to the transplant community.[234] If analysis

[233] Liyanage, L.N., Akizhanov, D., Patel, S.S., Segev, D.L., Massie, A.B., Stewart, D.E., & Gentry, S.E. (in press). Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. *American Journal of Transplantation. https://doi.org/10.1016/j.ajt.2024.08.016.*

[234] OPTN. (2023, September 14). New pre-transplant performance metric now in effect, offer acceptance rate ratio. Retrieved August 15, 2024

results warrant a new or updated policy, we will address it pursuant to future rulemaking.

Additionally, we believe SRTR methodology, or more generally the organ offer acceptance rate ratio, ensures balance in the model. While the achievement domain focuses on increasing kidney transplant volume, the efficiency domain metrics focuses on efficient utilization of kidney transplants to reduce organ non-use. By optimizing filters, IOTA participants are ensuring that their kidney transplant waitlist patients that are active on the transplant waitlist will actually be transplanted. Additionally, we believe organ filters allow kidneys to be directed to the appropriate kidney transplant hospital to improve quality of organs (lesser cold ischemic time) and potentially increase volume of transplants due to a more efficient process.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing, without modification, at § 512.426(b)(1) our proposals to use and calculate the OPTN organ offer acceptance rate ratio in accordance with OPTN's measure specifications and SRTR's methodology as the metrics that would determine IOTA participants' performance on the efficiency domain. Additionally, we are finalizing as proposed the definitions of match run, missing responses, and bypassed response at § 512.402.

(b) Calculation of Points

As described in section III.C.5.b. of the proposed rule, we proposed that performance on the efficiency domain would be worth up to 20 points of 100 maximum points. As indicated in section III.C.5.c.(2). of this final rule, the efficiency domain is weighted lower than the achievement domain but equal to the quality domain to ensure performance measurement is primarily focused on increasing number of kidney transplants, while still incentivizing efficiency and quality. Within the efficiency domain, we proposed that the OPTN organ offer acceptance rate ratio would account for the entirety of the 20 allocated points in that domain.

In section III.C.5.d.(1).(b) of the proposed rule, we proposed applying a two-scoring system to award up to 20 points to the IOTA participant based on its performance on the OPTN organ offer acceptance rate ratio. Under this two-scoring system, we would determine two separate scores for an IOTA participant: an ''achievement score'' reflecting its current level of performance, and an ''improvement score'' reflecting changes in its performance over time. We proposed that the IOTA participant would be awarded points equal to the higher of the two scores, up to a maximum of 20 points. We believed that this approach would recognize both high achievement among high performing IOTA participants as well as IOTA participants that make marked improvement in their performance. We believe that average or low-performing IOTA participants would likely require multiple years of transformation to catch up with those who have a high organ offer acceptance rate ratio.

In section III.C.5.d.(1).(b). of the proposed rule, for achievement scoring, we proposed that points earned would be based on the IOTA participants' performance on the organ offer acceptance rate ratio ranked against a national target,[235] inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants. Currently, there is a large disparity in organ offer acceptance ratio performance. As previously noted, a 2020 national registry study found that the probability of receiving a deceased donor kidney transplant within 3 years of waiting list placement varied 16-fold between different kidney transplant hospitals across the U.S.[236] Large variations were still present between kidney transplant hospitals that utilized the same OPO.[237] The probability of transplant was significantly associated with transplant hospitals' offer acceptance rates.[238]

We proposed that achievement scoring points be awarded based on the national quintiles, as outlined in Table 7 of section III.C.5.d.(1).(b). of this final rule. Utilizing quintiles aligns with the calculation of the upside and downside risk payments in relation to the final performance score, as detailed in section III.C.6.c.(2). of this final rule, 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 was an upper limit to the benefits of efficiency, and quintiles combine the highest 20 percent of performers in a point band. Due to the current disparity among kidney transplant hospitals on this metric, we did not expect every IOTA participant to reach top-level performance.

In the proposed rule, we proposed the following Organ Offer Acceptance Rate Achievement point allocation for IOTA participants, as illustrated in Table 7 of section III.C.5.d.(1).(b). of this final rule:

- 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 the 60th percentile of performers, 10 points.
- IOTA participants in the 20th to below the 40th percentile of performers, 6 points.
- IOTA participants who are below the 20th percentile of performers, 0 points.

from *https://optn.transplant.hrsa.gov/news/new-pre-transplant-performance-metric-now-in-effect-offer-acceptance-rate-ratio/*.

[235] Subsequent to the publication of the proposed rule, we found that.

[236] 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*.

[237] 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*.

[238] Ibid.

TABLE 7: ORGAN OFFER ACCEPTANCE RATE ACHIEVEMENT SCORING

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
80th Percentile relative to target OR for comparison	Equals 80th percentile	Greater than 80th percentile	20
60th Percentile	Equals 60th percentile	Less than 80th percentile	15
40th Percentile	Equals 40th percentile	Less than 60th percentile	10
20th Percentile	Equals 20th percentile	Less than 40th percentile	6
20th Percentile	N/A	Less than 20th percentile	0

As discussed in section III.C.5.d.(1).(b). of the proposed rule, we considered the approach used by the MPSC, that would yield maximum points if transplant hospitals have at least a .35 organ offer acceptance rate ratio. However, we do not believe that this approach fits with the IOTA Model's goals. MPSC metrics are more focused on highlighting and improving performance for the lowest performers, whereas the model seeks to improve performance across the board, not just avoid poor performance.

For improvement scoring, we proposed in section III.C.5.d.(1).(b). of the proposed rule, that points earned would be based on the IOTA participants' performance on organ offer acceptance rate ratio during a PY relative to their performance during the third baseline year for the PY that is being measured. We proposed to use the same baseline year definition used for participant eligibility, as described in section III.C.3. of the proposed rule, including the rationale for doing so. We separately proposed to calculate an ''improvement benchmark rate,'' defined as 120 percent of the IOTA participants' performance on the organ offer acceptance rate ratio during the third baseline year for each PY. We would award points by comparing the IOTA participant's organ offer acceptance rate ratio during the PY to the IOTA participant's improvement benchmark rate to determine the improvement scoring points earned. Specifically:

- IOTA participants whose organ offer acceptance rate ratio during a PY is at or above the improvement benchmark rate would receive 12 points.
- IOTA participants whose organ offer acceptance rate ratio during a PY is at or below the organ offer acceptance rate ratio during the third baseline year for that respective PY would receive no points.
- IOTA participants whose organ offer acceptance rate ratio during a PY is greater than the organ offer acceptance rate ratio during the third baseline year for that respective PY, but less than the improvement benchmark rate, would earn a maximum of 12 points in accordance with Equation 3.

Equation 3: Proposed Improvement Scoring for Organ Offer Acceptance Rate Ratio

$$Organ\ Offer\ Acceptance\ Rate\ Ratio\ Improvement\ Scoring\ =$$

$$12\ x \frac{Rate\ Earned\ in\ Performance\ Year\ -\ Rate\ Earned\ in\ Third\ Baseline\ Year}{Benchmark\ Rate\ -\ Third\ Baseline\ Year\ Rate}$$

As discussed in section III.C.5.d.(1).(b). of the proposed rule, we proposed using Equation 3 to mirror the methodology used in the Hospital Value Based Purchasing (VBP) Program, with the only modification being the number of points available for this metric. Equation 3 would also allow for a maximum of 12 points to be earned by IOTA participants whose organ offer acceptance rate ratio during the PY is greater than the baseline year organ offer acceptance rate ratio but less than the improvement benchmark rate. We did not want the improvement score to be worth more than, or equal to, the achievement score, as proposed for the organ offer acceptance rate ratio performance scoring, so as to reserve the highest number of points (15 points) for top performers in the metric.

Once both the achievement score and the improvement score were calculated, we proposed, in section III.C.5.d.(1).(b). of the proposed rule, comparing the two scores and applying the higher of the two values as the performance score or points earned (of 20 possible points) for the organ offer acceptance rate ratio metric within the efficiency domain.

In section III.C.5.d.(1).(b). of the proposed rule, we considered setting the improvement benchmark rate to be 200 percent of the IOTA participant's third baseline year for a given PY to measure performance on the organ offer acceptance rate ratio. The scoring structure would be the same, with 12 or 0 points to be awarded depending on whether the benchmark is met. However, we believed this would be too strict and risk penalizing already high-achieving IOTA participants.

In section III.C.5.d.(1).(b). of the proposed rule, we considered simplifying the performance scoring for the organ offer acceptance rate ratio metric within the efficiency domain by only awarding performance points based on the proposed achievement scoring methodology, rather than also calculating an improvement score for the IOTA participant and comparing the scores. However, given the variation that is present amongst kidney transplant hospitals, we thought it might be difficult for some IOTA participants to achieve top tier points for the first two model PYs. Thus, incorporating an improvement scoring method would ensure that IOTA participants are still rewarded for improvements made towards the efficiency domain goal.

We considered using the scoring method proposed for the post-transplant outcomes metric within the quality domain, as described in section III.C.5.e.(1)(b) of the proposed rule, as it would award full points if the hazard ratio or confidence interval of the metric includes the number one or higher. We believed this scoring method would honor the intent of the organ offer acceptance rate ratio metric, which is to determine if an IOTA participant is accepting more organs than expected. However, given the variation in

performance on this metric across all kidney transplant hospitals, we believe improvement opportunities exist in this metric. We also believe that our proposed approach rewards both achievement and improvements and is a more rigorous scoring methodology.

As discussed in section III.C.5.d.(1).(b). of the proposed rule, we considered a continuous scoring range from zero to 20, where IOTA participants may earn a score of any point value instead of bands. We thought that a continuous scoring range could provide more flexibility for IOTA participants and greater variety of scores. However, we believe grading using bands provides a more favorable scoring system for IOTA participants by grouping performance. We also recognize there is diminishing marginal efficiency for higher and higher organ offer acceptance rate ratios.

We considered using the lower and upper bounds of the offer acceptance odds ratio within a confidence interval, like we proposed in the quality domain for post-transplant outcomes, as described in section III.C.5.e.(1).(b). of the proposed rule. However, the organ offer acceptance rate ratio metric, unlike post-transplant outcomes, had wider disparity in performance than in post-transplant outcomes. We believe that there is a clear benefit to patients and the transplantation ecosystem overall by continuing to increase performance on this metric and promoting better performance than the national average. Under this alternative, IOTA participants would be evaluated based on whether the lower bound, acceptance ratio, and upper bound all crossed 1. Doing so would indicate the IOTA participant's true offer acceptance ratio with 95 percent probability. We did not propose this approach, however, as our analyses using SRTR data indicated that the majority of kidney transplant hospitals had either all three bounds cross 1 or all three never cross 1. Thus, scoring would largely not have differed from utilizing the offer acceptance ratio alone.

Finally, in section III.C.5.d.(1).(b). of the proposed rule, we also considered stratifying offer acceptance by KDRI status, with different score targets based on KDRI status ranges, such as KDRI of less than 1.05, between 1.05 and 1.75, and more than 1.75. We thought that this scoring method may potentially prevent IOTA participants from narrowing their criteria to only receive selected offers. However, we believed that it was already risk adjusted for organ status inherently in the measure because only organs that are ultimately transplanted are counted in the denominator.

We sought comment on our proposed organ offer acceptance rate ratio performance scoring methodology for purposes of assessing efficiency domain performance for each IOTA participant, including on the achievement and improvement score calculation and point allocation method. We also seek comments on alternatives considered.

The following is a summary of comments received on our proposed scoring methodology for the organ offer acceptance rate ratio performance in the efficiency domain and our responses:

Comment: Several commenters relayed concern that there may be a typo in the proposed rule, which stated the highest amount of points for the efficiency domain is 15.

Response: We thank the commenters for identifying a typo in the proposed rule. The highest amount of points available for IOTA participants to earn is 20 points if they are in the highest quintile of the organ offer acceptance rate ratio achievement score.

Comment: There were numerous comments about scoring methodology. Several commenters requested clarification as to why the improvement component of the efficiency domain does not provide more than 12 points. A couple of commenters had specific concerns that quintile methodology is not ideal and creates uncertainty. A commenter was concerned that improvement score of the efficiency domain does not account for high performers who may have challenges improving every year.

Response: Thank you for seeking clarification. An improvement goal was selected in addition to an achievement goal to account for the variation among kidney transplant hospitals and in acknowledgement that it may be challenging for some kidney transplant hospitals to reach high performance levels in the achievement component of the efficiency domain. In the proposed rule, we chose not to provide maximum points in the improvement domain, in order to reward the top-tiered programs in efficiency performance. Additionally, if some kidney transplant hospitals newly utilize filters, while others have already been utilizing filters, this will increase their improvement score significantly. By limiting improvement points, this prevents mismatch in recognizing those who newly and previously utilize filters.

We note that we are finalizing these policies as proposed but with a minor technical correction to update the maximum number of points awarded for improvement scoring from 12 points to 15 points. In the proposed rule at 89 FR 43560, we proposed to award IOTA participants whose organ offer acceptance rate ratio during a PY is at or above the improvement benchmark rate would receive 12 points. We also proposed at 89 FR 43560 that IOTA participants whose organ offer acceptance rate ratio during a PY is greater than the organ offer acceptance rate ratio during the third baseline year for that respective PY, but less than the improvement benchmark rate, would earn a maximum of 12 points in accordance with equation 1 to paragraph (c)(1)(ii)(B)(*1*) of § 512.426. However, we also stated at 89 FR 43560 that we did not want the improvement score to be worth more than, or equal to, the achievement score, as proposed for the organ offer acceptance rate ratio performance scoring, so as to reserve the highest number of points (15 points) for top performers in the metric. Thus, we are updating the regulation text at § 512.426(c)(1)(ii)(B)(1) to reflect 15 points instead of 12 points and equation 1 to paragraph (c)(1)(ii)(B)(*1*) of § 512.426, as illustrated in equation 4 below, to reflect a multiplier of 15 instead of 12.

Equation 4: Improvement Scoring for Organ Offer Acceptance Rate Ratio

$$Organ\ Offer\ Acceptance\ Rate\ Ratio\ Improvement\ Scoring\ = 15\ x \frac{Rate\ Earned\ in\ Performance\ Year - Third\ Baseline\ Year\ Rate}{Improvement\ Benchmark\ Rate - Third\ Baseline\ Year\ Rate}$$

Additionally, the commenters are correct that the methodology creates a moving target for rankings within the scoring quintiles, year to year. This method was chosen to ensure that targets reflect current practices and

trends across kidney transplant hospitals.

We also note that we are finalizing this policy as proposed but with a minor technical correction to update the terminology used to provide points for achievement scoring in the efficiency domain. In the proposed rule at 89 FR 43559, we proposed that achievement scoring, would be based on the IOTA participant's performance on the organ offer acceptance rate ratio ranked against a national target, inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants. However, we also stated at 89 FR 43559 that achievement scoring points be awarded based on the national quintiles, as outlined in Table 6 of section III.C.5.d.(1).(b). of the proposed rule. Thus, we are updating our regulation text at § 512.426(c)(2)(i) to remove the reference to performance being measured against a national target and instead based on national ranking.

Based on PY 1 and ongoing feedback, we will consider in future rulemaking if there should be alternative point opportunities for the efficiency improvement scoring scale in later performance years. If analysis results warrant a new or updated policy, we will address it pursuant to future rulemaking.

Comment: A couple of commenters were concerned that IOTA participants may accept deceased donor organs more aggressively or make their waitlist criteria more stringent, to have a high score in the efficiency domain due to the percentile scoring.

Response: We agree that some IOTA participants with higher risk thresholds may accept deceased donor organs more aggressively, if they believe they have the resources and support for their patients post-transplant. While this may apply to some kidney transplant hospitals, however, we do not believe that this will be a common approach. IOTA participants have the opportunity to consider utilizing filters that more closely match their risk threshold and waitlist patient population. While we do not believe that the efficiency domain will make waitlist criteria more stringent, we do believe that paired with the transparency notification requirement in section III.C.8.a(2), IOTA participants may be more inclined to remove patients from their active waitlist who are not potential kidney transplant candidates. Should we notice an adverse effect of the efficiency domain, such as reduction in access to waitlisting or being active on the waitlist, we will take this into consideration for future rulemaking. Additionally, as mentioned in the comments noted previously in this section, we are we are updating our regulation text at § 512.426(c)(2)(i) and in Table 1 to Paragraph (c)(1)(i) at our regulation at § 512.426 to remove reference to performance being measured against a national target and is instead based on national ranking.

Comment: A few commenters suggested considerations for the efficiency domain scoring. These considerations included ensuring not to penalize IOTA participants that are already accepting more organs than expected, moderating the proposed expectations for performance in the achievement and improvement scores, and aligning the efficiency domain point system to SRTR's upcoming method of creating performance tiers. Several commenters also provided suggestions for alternative criteria for kidney transplant hospitals to receive the full 20 points in the efficiency domain. The suggestions included awarding full points for meeting the OPTN's minimum ratio, having an organ offer acceptance ratio of 1.0, and meeting organ acceptance expectations. There were also a few suggestions that kidney transplant hospitals that meet the improvement component criteria should be awarded the full 20 points as well; this could potentially be accomplished by having programs opt in to either an achievement or improvement track. Finally, a commenter pointed out that because the organ offer acceptance rate ratio is compared to national performance for the achievement component of the efficiency domain, a program may improve its rate but not its ratio depending on the national rate. They same commenter suggested considering relative acceptance rate. Similarly, a commenter stated the scoring system, as proposed, is too harsh.

Response: We thank the commenters for their feedback. As mentioned in the proposed rule, we do not expect every IOTA participant to reach top-level performance. If an IOTA participant is already accepting more organs than expected, they will likely have a high scoring ratio as well. An IOTA participant that scores in the 50th percentile of performance for the organ offer acceptance rate achievement score would receive 10 out of 20 points. Alternatively, if an IOTA participant improves their organ offer acceptance rate ratio by 120 percent of their benchmark rate, as proposed, they can earn 15 points. As mentioned in the comments noted previously in this section, we are finalizing our proposed organ offer acceptance rate ratio improvement scoring methodology to reflect that the maximum number of points awarded for improvement scoring is 15 points, rather than 12 points.

For PY 1, we believe it is appropriate to carve out more points for those IOTA participants who have the highest performance. We do not believe the OPTNs minimum ratio is high enough to nudge transplant programs to continue to improve on this performance metric. As mentioned in the comments noted previously in this section, we are finalizing our proposed organ offer acceptance rate ratio achievement scoring methodology with slight modifications to reflect that points earned will be based on national ranking rather than a national target.

Although we did not consider the SRTRs performance tier assessment in the proposed rule, we are interested to learn more about this methodology once implemented and to further consider this for future rulemaking. We will also continue to consider if the improvement maximum score should be equivalent to the achievement maximum score and if achieving upper quintile ranks is too challenging. This, in addition to ongoing feedback and performance during PY 1 will help guide us in future rulemaking.

Comment: A commenter was concerned that the organ offer acceptance rate ratio would be impacted by transplant programs completing dual organ transplants, who may receive priority offers.

Response: We thank the commenter for their feedback and recommends reviewing Table 6 of section III.C.5.d(1)(a) of this final rule, which includes organ offers included and excluded from the organ offer acceptance rate ratio metric. This specifically identifies that offers to multi-organ candidates (except kidney pancreas candidates that are also listed for kidney alone) are excluded from the measure.

Comment: A few commenters were concerned about overall impact of risks and costs of the organ offer acceptance ratio methodology. A couple of commenters were concerned that point allocation for the organ offer acceptance rate ratio and kidney transplant volume will increase marginal kidney use and have higher financial costs and risks to patients. A commenter specifically asked whether there will be subsequent increase in reimbursement and SRTR adjustments. Similarly, another commenter stated that the organ offer acceptance ratio incentivizes IOTA participants to accept offers they may not ordinarily accept and is concerned that the IOTA Model needs to minimize

the risk of adverse outcomes when evaluating participating hospitals fairly.

Response: We thank the commenters for sharing their concerns. We agree that some IOTA participants may choose to increase their utilization of DCD kidneys or kidneys with a KDPI greater than 85, however, this is a choice for each IOTA participant based on their comfort level and resources and is not the only way for an IOTA participant to perform well in the IOTA Model. Regardless of the approach of each IOTA participant, we intend to monitor for unintended consequences that my occur with the model. We bring attention to the fact that while IOTA participants who achieve a final performance score of 60 or more points will receive an upside risk payment, as described and finalized in section III.C.6.c(1) of this final rule, there is also a neutral zone for IOTA participants who achieve a final performance score between 0 and 59 points in PY 1 and a final performance score of 40–59 points in PY 2 through PY 6, as described and finalized in section III.C.6.c(1) of this final rule. We direct readers to sections III.C.6 of this final rule for a full discussion on payment. With increasing resources and knowledge such as access to timely donor biopsies and research on what factors prompt kidneys to be designated as high KDPI kidneys, there are growing opportunities in the transplant ecosystem to identify kidneys that may or may not be ideal to transplant.

As for as modifications to SRTR adjustments and reimbursement, we will continue to collaborate with other groups in OTAG to work on aligning goals across the transplant ecosystem.

Comment: A few commenters had concerns that IOTA participants may change their habits or manipulate their listing or transplant practices to improve their organ offer acceptance rate. Specifically, a couple of commenters conveyed their concern that kidney transplant hospitals will use organ offer filters to have a better offer acceptance rate ratio, whereas kidney transplant hospitals that utilize marginal kidneys and try to have higher volumes will have worse performance for this ratio. They requested clarification on how CMS will prevent IOTA participants from being rewarded if they choose to use filters for this metric. Another commenter stated their concern that to achieve a better organ offer acceptance ratio, IOTA participants may inactivate patients, causing subsequent disadvantages. Additionally, a commenter was concerned that OPOs may start bypassing IOTA participants if they scrutinize whether the organ is an optimal match for a recipient.

Response: We appreciate the commenters' feedback and believe that organ offer filters are often an underutilized resource that help minimize organ non-use, out-of-sequence allocation, and prolonged cold ischemic times. Therefore, we disagree with the commenter views and encourage kidney transplant hospitals to use filters to reduce unnecessary offers to their transplant programs, when appropriate, for categories of offers that the transplant program will definitively not accept. We recognize this may be challenging due to high thresholds for marginal kidneys or different risk thresholds for different rotating surgeons in the same transplant program. However, we believe that given the rise in organ offers made by OPOs, there is opportunity to reduce administrative burden and organ non-use, by way of using filters and impacting their organ offer acceptance rate.

We acknowledge that there are some unique cases that are very high risk and require specific donor and recipient criteria, which may impact acceptance practices. We also acknowledge that it is unrealistic for kidney transplant hospitals to accept every offer they receive.

If OPOs start bypassing IOTA participants due to in depth analysis of whether an organ is optimal for their patients, we believe this would be important model feedback for IOTA participants to relay to us. If analysis results warrant a new or updated policy, we will address it pursuant to future rulemaking.

Comment: A commenter suggested CMS mandate the use of organ offer filters by a certain date.

Response: We appreciate the commenter's suggestion. Currently, we do not believe mandating organ filters is appropriate for the IOTA Model. While the performance domains and performance metrics in the IOTA Model do indirectly encourage use of organ offer filters, we believe IOTA participants should have the opportunity to identify what organ offer filters are appropriate for their transplant program and the populations they serve, as they participate. This is a topic for the entire transplant ecosystem to collectively consider in the future.

Comment: A few commenters conveyed concerns that unique situations may impact post-transplant outcomes and impact acceptance rates. For example, a commenter stated that CMS should consider patient characteristics and how they impact a successful transplant. Another commenter is concerned that not all offers are viable. A commenter conveyed concern that filter settings for distance may conflict with allocation registered distance. For example, a kidney available in Alaska may show as local per UNOS assignment but will show as 2500 miles away from a kidney transplant hospital in Washington per filters, which would require liberal filters for distance, to capture donors in that region.

Response: We appreciate the commenters bringing these concerns to our attention. We acknowledge that there are unique donor and recipient characteristics that may impact offer acceptances. We do not expect that any IOTA participant will accept every organ offer it receives since there are scenarios that are difficult to predict.

We agree with the second commenter who stated that not all offers are viable and acknowledges this in section III.C.5.d.(1)(a), Table 6, where exclusions for the organ offer acceptance rate ratio metric are included. Kidney match runs that have no acceptances are excluded in this metric.

We appreciate the commenter bringing UNOS and offer filter distance criteria mismatch to our attention. This was not considered at the time of the proposal of the IOTA Model. We plan to further discuss this internally and analyze how this can appropriately be accounted for in future performance years.

Comment: A commenter requested that CMS consider how IOTA participants using organ offer filters prior to the model will be compared to IOTA participants that newly utilize organ offer filters and receive higher scores in the efficiency domain.

Response: We appreciate the commenter's feedback. The proposed organ offer acceptance rate ratio achievement scoring methodology is independent of pre-existing or new filter use and is strictly dependent on a ratio compared to national ranking. As mentioned in the comments noted previously in this section, we are finalizing our proposed achievement scoring methodology with slight modifications to reflect that points earned will be based on national ranking rather than a national target. Additionally, the organ offer acceptance rate ratio improvement scoring methodology has a ceiling of 15 points, which prevents IOTA participants that are new to using filters from having an unfair advantage over IOTA participants who previously utilized this resource. As mentioned in the comments noted

previously in this section, we are finalizing our proposed improvement scoring methodology to reflect that the maximum number of points awarded for improvement scoring is 15 points, rather than 12 points.

Comment: A commenter encouraged CMS to consider that not all kidney transplant hospitals have the same capabilities, and this contradicts the achievement component of the efficiency domain since kidney transplant hospitals are not uniform.

Response: We appreciate the commenter's concerns and acknowledge the differences between kidney transplant hospitals but also believe that these unique variations create flexibility in how an IOTA participant may choose to adapt practice to impact their organ offer acceptance rate ratio. For those IOTA participants who prioritize improving their own score year-to year, the organ offer acceptance rate ratio improvement scoring methodology, as described in section III.C.5.d.(1).(b). of this final rule, allows them to earn points independent of comparison to other IOTA participants.

Comment: A commenter relayed concern that keeping track of potential offers and acceptances is burdensome.

Response: We appreciate the commenter's feedback and will take this into consideration when planning for and implementing the IOTA Model in addition to identifying appropriate intervals for IOTA participants to have access to interim results. The IOTA Model does not mandate that IOTA participants keep track of their potential organ offers and acceptances but understands that IOTA participants may want to have access to this information for personal tracking purposes.

Comment: A couple commenters expressed their support for CMS' proposal to include the organ offer acceptance rate ratio as a performance measure in the efficiency domain. They contended that the organ offer acceptance rate ratio metric motivates kidney transplant hospitals to utilize filters that reflect their acceptance practices, while also providing the flexibility to modify these filters. Furthermore, they suggested that this metric would encourage increased acceptance rates.

Response: We appreciate the support received from commenters for our proposal to include the organ offer acceptance rate ratio metric as a performance measure in the efficiency domain.

After consideration of the public comments, for the reasons set forth in this rule, we are finalizing the proposed provisions for the point allocation and calculation methodology for efficiency domain scoring and scoring for organ offer acceptance rate ratio for the IOTA Model at § 512.426(c), with slight modifications. In the proposed rule at 89 FR 43559, we proposed that achievement scoring points be awarded based on the national quintiles, as outlined in Table 6 of section III.C.5.d.(1).(b). of the proposed rule. As such, we are updating our regulation text at § 512.426(c)(2)(i) and in Table 1 to Paragraph (c)(1)(i) at our regulation at § 512.426 to remove reference to performance being measured against a national target and is instead based on national ranking. Additionally, we are updating the regulation text at § 512.426(c)(1)(ii)(B)(1) to reflect 15 points instead of 12 points and updating the multiplier in equation 1 to paragraph (c)(1)(ii)(B)(*1*) at § 512.426, as illustrated in Equation 4 in this section, to reflect 15 instead of 12. Lastly, we are updating our regulation text language at § 512.402 to clarify our definition for improvement benchmark rate, which we modified to 120 percent of the IOTA participants' performance on the organ offer acceptance rate ratio, as specified under § 512.426(c)(1)(ii)(A) rather than 120 percent of the IOTA participants' performance on organ offer acceptance rate ratio, as specified under § 512.426(c)(1)(ii)(A).

e. Quality Domain

In the proposed rule, we proposed to define ''quality domain'' as the performance assessment category in which CMS assesses the IOTA participant's performance using a performance measure and quality measure set focused on improving the quality of transplant care, as described in section III.C.5.e of the proposed rule and section III.C.5.e. of this final rule. We proposed that performance on the quality domain would be worth up to 20 points out of the proposed 100 points. The quality domain is focused on monitoring post-transplant care and quality of life for IOTA transplant patients.

In section III.C.5.e of the proposed rule, we stated that our goal for the quality domain within the IOTA Model is to achieve acceptable post-transplant outcomes while incentivizing increased kidney transplant volume. We believed 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. Therefore, we proposed to include one post-transplant outcome measure, as described in section III.C.5.e(1) of this final rule, and a quality measure set that includes two patient-reported outcome-based performance measures (PRO–PM) and one process measure, as described in section III.C.5.e(2) of this final rule.

We sought comment on the proposed definition of the quality domain.

We did not receive any comments on the proposed definition of the quality domain and are finalizing the proposed definition for quality domain at § 512.402, with slight modification to remove the following words from the definition: and quality measure set. Since we are not finalizing our proposal to include our proposed quality measure set that includes two patient-reported outcome-based performance measures (PRO–PM) and one process measure, as described in the section III.C.5.e(2) of this final rule, we modified the quality domain definition and removed reference to the quality measure set. As such, we are also finalizing the general provisions for the quality domain as proposed, with a minor technical correction to update the cross reference in the regulation text at § 512.424(a). Specifically, we are removing the cross reference to the proposed quality measure set at § 512.424(a). We direct readers to section III.C.5.e(2) of this final rule for further discussion on our proposed quality measure set methodology. We are also finalizing our regulation as proposed without modification at § 512.424(b) that for each PY, CMS assesses each IOTA participant using the specified quality metrics. Lastly, we direct readers to section III.C.5.e(1) of this final rule for further discussion on our proposed post-transplant outcome measure.

(1) Post-Transplant Outcomes

In the proposed rule, we proposed using an unadjusted rolling ''composite graft survival rate,'' defined as the total number of functioning grafts relative to the total number of adult kidney transplants performed, as described in the proposed rule (89 FR 43518) and section III.C.5.e(1)(a) of this final rule, to assess IOTA participant performance on post-transplant outcomes. In this measure, the numerator (observed functioning grafts) and denominator (number of kidney transplants completed) would increase each PY of the IOTA Model to include a cumulative total.

In section III.C.5.e(1) of the proposed rule, we stated that over the past few decades, advances in immunosuppressive therapies, surgical techniques, and organ preservation

methods have resulted in significant improvements in kidney transplantation outcomes.[239] According to the OPTN, the overall 1-year survival rate for kidney transplantation recipients in the United States is over 90 percent, and the 5-year survival rate is around 75 percent. However, even with the advances that have been made to improve kidney outcomes, the success of kidney transplantation is still dependent upon factors such as the age and health of the donor and recipient, the presence of comorbidities (for example, diabetes), and the effectiveness of the immunosuppressive regimen. Kidney transplant outcomes can also be affected by possible post-transplant complications, including infection, cardiovascular disease, and kidney failure.[240]

More recently, CMS received feedback from transplant hospitals, patient advocacy groups, and transplant societies, including on the recent rule making (''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction'' (83 FR 47686)), that the 1-year measure was causing transplant centers to be risk averse about the patients and organs they would transplant while being simultaneously topped out (83 FR 47706).[241] Notably, even the lowest ranked programs, as measured by the SRTR, achieved a result of 90 percent of transplanted patients have a functioning graft at one year.[242]

To safeguard patient outcomes under the IOTA Model, we proposed to include this measure as a checkpoint (89 FR 43518). Because there is significant variation in post-transplant outcomes across kidney transplant hospitals, we believed the IOTA Model should promote improvement in outcomes for the benefit of attributed patients. We also believed that this measure would build upon, and complement, existing OPTN and SRTR measures to the maximum extent possible. Additionally, we believed that this approach could be applied with minimal adaptation to other organs were they to be added to the model through future rulemaking. Furthermore, we believed that this measure would enhance patient understanding of clinically important post-transplant outcomes beyond existing 90-day, 1-year and 3-year post transplant outcomes.

We considered measuring post-transplant outcomes using SRTR's methodology at 90 days,[243] and constructing 5-year and 10-year post-transplant measures (89 FR 43518). However, we did not select these measures because post-transplant outcomes are already measured at 90-days by SRTR. Additionally, because the IOTA Model as proposed spans only 6 years, we did not believe we could appropriately measure post-transplant outcomes at 5 or 10 years.

We considered constructing an ongoing post-transplant outcome measure that would continuously evaluate post-transplant outcomes at 1-year throughout the model performance period of the IOTA Model. In this measure the numerator (observed graft failures) and denominator (number of transplants completed) would increase each PY of the model to a cumulative total (89 FR 43518). For example, in PY 1 of the model an IOTA participant could have five 1-year observed graft failures and complete 20 transplants, resulting in a graft failure rate of 0.25. In PY 2 of the model, the same IOTA participant could have eight 1-year observed graft failures and complete 30 transplants. To calculate the IOTA participant's graft failure rate for PY 2 of the model, we would divide the cumulative total of 13 1-year observed graft failures by the cumulative total of 50 completed transplants. However, we felt it was important to measure post-transplant outcomes in terms of graft survival rather than in terms of graft failure. We acknowledged that for the purposes of measuring graft survival using OPTN data, use of either concept would generate the same outcome measurement because OPTN data identify graft status as either functioning or failed. However, we aim to convey the importance of ongoing management to preserve the health of the transplanted graft and the health and quality of life of the attributed patients.

We considered constructing a continuous patient survival measure that would evaluate patient survival throughout the entirety of the IOTA Model (89 FR 43518). Similar to the considered measure mentioned in the previous paragraph, the numerator (number of patients alive) and denominator (number of received kidney organ offers) would increase each PY of the model to a cumulative total. For the denominator, we considered only including organ offers where the sequence number was less than 100 or less than 50. In other words, under that rationale we would only include offers that came within a certain point of time that could have potentially benefited the patient or should not have been turned down. We believed that this type of measure would not disincentivize waitlisting and could potentially increase equity within this population. Additionally, we believed that this type of measure would indirectly encourage living donor transplants because those would only hit the numerator (number of people alive) but not the denominator (number of kidney organ offers received). However, we felt that this measure would be somewhat duplicative of other parts of the model where we are already evaluating organ offer acceptance. We also chose not to propose this measure due to logistical concerns, and felt that it could be difficult to determine how many people were offered a specific organ and determining what an appropriate sequence number cutoff should be.

We considered measuring estimated glomerular filtration rate (eGFR) at the 1-year anniversary of the date of transplant (89 FR 43518). Glomerular filtration rate (GFR) is a way to assess renal function, and eGFR is the test used to assess renal function in primary

[239] Stewart, D.E., Garcia, V.C., Rosendale, J.D., Klassen, D.K., & Carrico, B.J. (2017). Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. *Transplantation, 101*(3), 575–587. *https://doi.org/10.1097/tp.0000000000001539;* Vinson, A., Kiberd, B.A., & Karthik Tennankore. (2021). *In Search of a Better Outcome: Opting Into the Live Donor Paired Kidney Exchange Program. 8,* 205435812110174–205435812110174. *https://doi.org/10.1177/2054358121101741 2;* Shepherd, S., & Formica, R.N. (2021). *Improving Transplant Program Performance Monitoring. 8*(4), 293–300. *https://doi.org/10.1007/s40472-021-00344-z.*

[240] Gioco, R., Sanfilippo, C., Veroux, P., Corona, D., Privitera, F., Brolese, A., Ciarleglio, F., Volpicelli, A., & Veroux, M. (2021). Abdominal wall complications after kidney transplantation: A clinical review. *Clinical Transplantation, 35*(12), e14506. *https://doi.org/10.1111/ctr.14506;* Wei, H., Guan, Z., Zhao, J., Zhang, W., Shi, H., Wang, W., Wang, J., Xiao, X., Niu, Y., & Shi, B. (2016). Physical Symptoms and Associated Factors in Chinese Renal Transplant Recipients. *Transplantation Proceedings, 48*(8), 2644–2649. *https://doi.org/10.1016/j.transproceed.2016.06.052;* Mehrabi, A., Fonouni, H., Wente, M., Sadeghi, M., Eisenbach, C., Encke, J., Schmied, B.M., Libicher, M., Zeier, M., Weitz, J., Büchler, M.W., & Schmidt, J. (2006). Wound complications following kidney and liver transplantation. *Clinical Transplantation, 20*(s17), 97–110. *https://doi.org/10.1111/j.1399-0012.2006.00608.x.*

[241] Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (September, 20, 2018) *https://www.federalregister.gov/documents/2018/09/20/2018-19599/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and.*

[242] Scientific Registry of Transplant Recipients. Request for Information. Requested on 05/02/2023. *https://www.srtr.org/.*

[243] Mpsc-enhance-transplant-program-performance-monitoring-system_srtr-metrics.pdf. (n.d.). Retrieved December 28, 2022, from *https://optn.transplant.hrsa.gov/media/qfuj3osi/mpsc-enhance-transplant-program-performance-monitoring-system_srtr-metrics.pdf.*

clinical care.[244] Despite the fact that studies indicate eGFR's potential as a reliable predictor of long-term post-transplant prognosis, our goal is to adopt a measure that resonates more with the transplant community's evaluation of post-transplant outcomes.[245] We recognized that the equation for calculating eGFR was revised in 2021 to not include race, but we still have some concerns over the potential for bias and inaccurate results and the limitations that still exist with the updated equation and did not believe it was appropriate to propose.[246]

We considered constructing several hospital-based post-transplant outcome measures such as those that measure: the number of days spent out of the hospital post-transplant, how many days spent at home post-transplant before returning to work, and number of hospital readmissions post-transplant (89 FR 43518). However, we do not want to penalize the use of moderate-to-high KDPI kidneys, as we recognize that utilizing these organs carries an increased risk of transplant recipient hospitalizations. Additionally, we had concerns over how we would assess and measure this type of metric.

We considered proposing a phased-in approach to measuring post-transplant outcomes, in which no post-transplant outcome metrics would be included until PY 3 of the model (89 FR 43518). In this alternative methodology, the quality domain for the first two PYs would only include our proposed quality measure set, as described in section III.C.5.e(2) of the proposed rule and this final rule. Starting PY 3 of the model, IOTA participants would be evaluated on two post-transplant outcome measures (SRTR's 1-year post-transplant outcome conditional on 90-day survival measure and 3-year post-transplant outcome measure) in addition to our proposed quality measure set. This approach incorporates a time delay, allowing us to assess the post-transplant outcomes of IOTA participants using SRTR's measures. Because we felt that it was critical to include a post-transplant measure from the onset of the model to check for unintended consequences throughout the entirety of the model performance period, we did not believe that this alternative was appropriate to propose.

We also considered using SRTR's new ''1-year post-transplant outcome conditional on 90-day graft survival'' measure and including a 3-year post-transplant outcome measure, such as the one currently used by SRTR (89 FR 43518). We also considered constructing our own 3-year post-transplant outcome measure conditional on 1-year survival. However we chose not to propose SRTR's conditional 1-year or 3-year post-transplant outcome measures or our own measure for the following reasons: (1) because SRTR's conditional 1-year metric has a 2.5 year lookback period, it would require us to evaluate IOTA participants on post-transplant outcomes prior to starting the model for at least the first two PYs; (2) because SRTR does not currently have a 3-year conditional post-transplant outcome measure, we would not be in alignment with SRTR if we constructed our own; (3) including SRTR's 3-year post-transplant outcome measure would include time outside of the model for at least the first three PYs and we want to evaluate IOTA participants based on their performance within the model; and (4) we recognize there may be some logistical issues and difficulty in measuring performance in that time. We may consider incorporating a 3-year post-transplant outcome measure into the model in the future, through rulemaking.

We sought public comment on our proposal to evaluate IOTA participants on post-transplant outcomes using our new composite graft survival rate metric, as well as on the alternatives we considered. We were also interested in public comment on how we may be able to use OPTN data to characterize different clinical manifestations of graft survival, as we understand that not all surviving grafts are clinically equivalent or have the same impact on the patient and graft health. We were further interested to hear from the public on which factors involved in graft survival are modifiable by the care team.

The following is a summary of the comments received on our proposal to evaluate IOTA participants on post-transplant outcomes using our new composite graft survival rate metric, as well as on the alternatives we considered and our responses:

Comment: There were many commenters requesting CMS use alternative metrics for graft survival rate that include risk adjustment methodologies in place of the proposed composite graft survival rate. For example, a commenter suggests that CMS develop additional post-transplant outcome measures that could be utilized to measure the quality of care provided, surrogates for long term allograft function, in addition to early indicators for allograft function. This commenter additionally recommended measures of kidney function at 12 months or new onset albuminuria (for example, urine albumin to creatinine ratio [ACR]). A couple commenters that suggested that CMS reconsider using eGFR at 12 months. Specifically, a commenter stated that, on a population level, the data suggests that eGFR at 12 months is predictive of long-term outcomes. Taking into consideration the dual goals of increasing organ utilization and patient outcomes, as well as outcomes that are superior to the dialysis, the same commenter recommended that an appropriate gauge of success in such a measure could be an eGFR superior to dialysis initiation or listing for re-transplant (for example, greater than 20 mL/min) such as 25 or 30 mL/min. Another commenter suggested that eGFR more accurately conveys long-term patient outcomes and incorporating granular measures of allograft function into performance metrics instead of using a binary (functioning/failed) indicator could improve patient care by prioritizing allograft function as a measure of program quality.

Several commenters urged CMS to reconsider current SRTR outcome measures. For example, although a commenter agreed with CMS that it may not be possible to use SRTR's 1-year graft survival conditional on 90-day survival or 3-year survival for short term evaluations of transplant program outcomes, they noted that SRTR has available models to assess 90-day outcomes along with the first full year posttransplant. The same commenter suggested that the 90-day models could be used to assess near-term success of the transplants in a risk-adjusted framework, and the full 1-year models could be used as the model develops and more performance years are

---

[244] Mayne, T.J., Nordyke, R.J., Schold, J.D., Weir, M.R., & Mohan, S. (2021). Defining a minimal clinically meaningful difference in 12-month estimated glomerular filtration rate for clinical trials in deceased donor kidney transplantation. *Clinical Transplantation, 35*(7), e14326. *https://doi.org/10.1111/ctr.14326.*

[245] Ibid; Wu, J., Li, H., Huang, H., Wang, R., Wang, Y., He, Q., & Chen, J. (2010). Slope of changes in renal function in the first year post-transplantation and one-yr estimated glomerular filtration rate together predict long-term renal allograft survival. *Clinical Transplantation, 24*(6), 862–868. *https://doi.org/10.1111/j.1399-0012.2009.01186.x;* Schold, J.D., Nordyke, R.J., Wu, Z., Corvino, F., Wang, W., & Mohan, S. (2022). Clinical events and renal function in the first year predict long-term kidney transplant survival. *Kidney360,* 10.34067/KID.0007342021. *https://doi.org/10.34067/kid.0007342021;* Hariharan, S., Mcbride, M.A., Cherikh, W.S., Tolleris, C.B., Bresnahan, B.A., & Johnson, C.P. (2002). Post-transplant renal function in the first year predicts long-term kidney transplant survival. *Kidney International, 62*(1), 311–318. *https://doi.org/10.1046/j.1523-1755.2002.00424.x.*

[246] Majerol, M., & Hughes, D.L. (2022, July 5). CMS Innovation Center Tackles Implicit Bias. *Health Affairs.* Retrieved January 16, 2024, from *https://www.healthaffairs.org/content/forefront/cms-innovation-center-tackles-implicit-bias.*

included to also incorporate risk adjustment into the evaluations.

This commenter also stated that the 90-day and 1-year models conditional on 90-day survival are currently used by the MPSC to evaluate transplant program outcomes. Therefore, they believed that not only is it feasible to use the 90-day and 1-year adjusted evaluations following the SRTR methodology, but it was also imperative to achieve the goals of the IOTA Model. Several commenters also urged CMS to use the outcomes already available from the SRTR, as it is well-established. Although the data is delayed, these commenters argued for CMS to include SRTR outcome measures citing reasons such as that it is well-established, accepted, and tested nationally and offers a comprehensive evaluation of graft survival that accounts for the complexities of both donors and recipients. A commenter believed CMS should remove the proposed measure and instead continue to use the existing SRTR post-transplant survival measures if CMS wants to increase the number of kidney transplants in part by encouraging kidney transplant hospitals to accept higher risk organs. This would also reduce the additional reporting burden associated with a new quality measure. Alternatively, a commenter suggested that CMS could utilize SRTR's CUSUM data as it could provide more real-time measurements.

Response: We thank the commenters for their suggestions on additional risk-adjusted measures that could be considered for measuring post-transplant outcomes in the model. As described at 89 FR 43562 in the proposed rule, we considered measuring eGFR at the 1-year anniversary of the date of transplant. However, our goal is to adopt a measure that better resonates with the transplant community's evaluation of post-transplant outcomes. As a result, we did not propose including eGFR at the 1-year anniversary. Additionally, we have ongoing concerns about potential bias, inaccurate results, and limitations with the updated eGFR equation. Given these issues, we did not believe it was appropriate to propose using eGFR at the 1-year mark.[247]

We also considered using SRTR's 1-year graft survival conditional on 90-day survival or 3-year post-transplant outcome measure. However, for the reasons stated at 89 FR 43562 in the proposed rule, we chose not propose using SRTR's 1-year graft survival conditional on 90-day survival or 3-year post-transplant outcome measure. As such, we will be finalizing our proposed composite graft survival rate metric to measure post-transplant outcomes in the IOTA Model. We will take into consideration the suggested post-transplant outcome metrics for IOTA and, if we determine that a new measure post-transplant outcome measure should be included, we would do so through future notice and comment rulemaking.

Comment: A commenter opposed the proposed graft survival rate measure given that the transplant community already has statistically valid measurements for outcomes utilizing a rolling 2.5-year cohort. Thus, the commenter felt relying on a raw calculation was not a reasonable replacement.

Response: We appreciate commenters recommendation to use an existing post-transplant outcome measure in place of the proposed composite graft survival rate. We will take the recommendation into consideration for future rulemaking and direct the commenter to comment responses noted previously in this section for further discussion on alternative metrics considered.

Comment: Several commenters expressed support for using the unadjusted Composite Graft Survival Rate as proposed—notably, that the proposed unadjusted composite graft survival rate is simple and would be easy for the patients to understand. For example, a commenter reported that their kidney patients frequently expressed confusion about transplant data metrics and appreciated CMS's efforts to establish a clearer measure for assessing graft survival. Furthermore, the commenter voiced support for using a graft survival metric rather than a graft failure metric, citing the reasons outlined in the proposed rule. A commenter also agreed with using this measure as a checkpoint to help ensure patient safety and improve understanding of post-transplant outcomes for patients. Another commenter concurred with CMS's proposal to calculate post-transplant outcomes using a rolling, unadjusted, composite graft survival measure. Although they believed that many commenters would argue for an urgent need to add ''risk adjustment'' to the measure, they felt that the proposed measure had the virtues of being straightforward, unambiguous, easy to understand, and easy to explain to patients and their families. This same commenter also stated their belief that these virtues are, too often, underemphasized.

Response: We thank the commenters for their support.

After consideration of the public comments received, for the reasons set forth in this rule, we are finalizing our proposed provision to assess IOTA participant performance on post-transplant outcomes using the composite graft survival rate at § 512.428(b)(1), without modification. We are also finalizing without modification the definition of composite graft survival rate at § 512.402.

(a) Calculation of Metric

In section III.C.5.e(1)(a) of the proposed rule, we proposed that for each model PY, CMS would calculate a composite graft survival rate for each IOTA participant, as defined and finalized in section III.C.5.e(1) of this final rule, to measure performance in the quality domain as described in section III.C.5.e. of this final rule.

In section III.C.5.e(1)(a) of the proposed rule, we proposed to use our own unadjusted composite graft survival rate equation to evaluate post-transplant outcomes. We proposed to calculate the composite graft survival rate by taking the total number of functioning grafts an IOTA participant has and dividing that by the total number of kidney transplants furnished to patients 18 years of age or older at the time of the transplant in PY 1 and all subsequent PYs (see Equation 4) to evaluate post-transplant outcomes during the IOTA Model performance period.

For example, as described in section III.C.5.e(1)(a) of the proposed rule, if in PY 1 of the model, an IOTA participant had 20 observed functioning grafts and furnished 25 kidney transplants to patients 18 years of age or older at the time of transplant, the composite graft survival rate for that IOTA participant would be 0.8 (20 from PY 1 divided by 25 from PY 1). Continuing this example, for PY 2 of the model if the same IOTA participant had 30 observed functioning grafts and furnished 35 kidney transplants to patients 18 years of age or older at the time of transplant, and two functioning kidney grafts failed from PY 1, CMS would calculate its composite graft survival rate for PY 2 as follows. CMS would divide the cumulative total of 48 observed functioning grafts (30 from PY 2 + 20 from PY 1—2 from PY 1) by the cumulative total of 60 completed kidney transplants (35 from PY 2 + 25 from PY 1), resulting in a

[247] Majerol, M., & Hughes, D.L. (2022, July 5). CMS Innovation Center Tackles Implicit Bias. *Health Affairs*. Retrieved January 16, 2024, from *https://www.healthaffairs.org/content/forefront/cms-innovation-center-tackles-implicit-bias.*

composite graft survival rate of 0.8 (48 divided by 60).

Equation 4: Composite Graft Survival Rate

$$Composite\ Graft\ Survival\ Rate\ = \frac{\#\ of\ Functioning\ Grafts}{\#\ of\ Completed\ Kidney\ Transplants}$$

In the proposed equation, the numerator (number of functioning grafts) is defined as the total number of living adult kidney transplant patients with a functioning graft. The numerator, functioning grafts, would exclude grafts that have failed, as defined by SRTR. 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.[248] OPTN follow-up forms are used to identify graft failure and re-transplant dates.[249] We also proposed to use OPTN adult kidney transplant recipient follow-up forms [250] to identify graft failure and re-transplant dates for all transplants furnished to kidney transplant patients 18 years of age or older at the time of the transplant. In the proposed equation, we noted that the numerator and denominator would not be limited to the attributed IOTA transplant patients. By this, we meant that it could include IOTA transplant patients who have been de-attributed from an IOTA participant due to transplant failure. We believed that IOTA participants could improve on this metric by working with IOTA collaborators to coordinate post-transplant care.

We considered incorporating a risk adjustment methodology to our proposed composite graft survival equation, such as the one used by SRTR for 1-year post-transplant outcomes conditional on 90-day survival or constructing our own (89 FR 43518). While we recognized that risk adjustment methodologies may help account for patient and donor traits, we could not find a risk adjustment approach that has consensus agreement within the kidney transplant community. We also believed that our proposed measure is inherently risk adjusted as it only counts organs that are ultimately transplanted to patients 18 years of age or older by a kidney transplant hospital.

We invited public comment on our proposed methodology to calculate post-transplant outcomes in the IOTA Model, and on alternatives considered. Although we proposed an unadjusted composite graft survival rate to measure post-transplant outcomes, we were interested in comments on whether risk risk-adjustments are necessary, and which ones, such as donor demographic characteristics (*i.e.,* race, gender, age, disease condition, geographic location), would be significant and clinically appropriate in the context of our proposed approach.

The following is a summary of the comments received on our proposed methodology to calculate post-transplant outcomes in the IOTA Model, on whether risk risk-adjustments are necessary, and which ones, such as donor demographic characteristics (*i.e.,* race, gender, age, disease condition, geographic location), would be significant and clinically appropriate in the context of our proposed approach, alternatives considered and our responses:

Comment: Commenters expressed concern that the lack of risk adjustment in the proposed composite graft survival rate metric could have adverse consequences and would add additional administrative burden. Many commenters expressed concern that the unadjusted composite graft survival rate does not account for the clinical risk factors of the recipient or the donor, therefore, it may inadvertently lead to disparities in transplant by incentivizing participants to select healthier patients. For example, a commenter felt that the absence of risk adjustment in the IOTA Model was problematic and could be detrimental to patient care; stating that without accounting for the varying complexities of patients' health conditions, hospitals might avoid referring higher-risk patients who could benefit most from transplants. Another commenter suggested that the lack of risk adjustment to the composite graft survival measure would incentivize IOTA participants to choose the healthiest patients to transplant and would reject those who are sensitized. Highly sensitized patients have high levels of anti-HLA antibodies, making them more likely to reject a kidney from a donor. These highly sensitized patients are more likely to be African American. This same commenter cited a study published in the Nephrology Dialysis Transplantation journal that found that highly sensitized kidney transplant recipients were more frequently African American compared to non-sensitized patients.[251] Thus, the commenter believed that failure to risk-adjust this measure could lead to outcomes that run counter to CMS's stated desire to reduce disparities. A commenter believed that the inclusion of a post-transplant graft survival metric is innate and relevant to the IOTA Model. However, the commenter stated that one of the longstanding frustrations of transplant programs is that various regulatory bodies use different definitions and standards for graft survival. As proposed, this would represent another new definition and benchmarking system for kidney graft survival. The same commenter also found the lack of risk-adjustment concerning, as they would be taking on donor organs and recipients of progressively higher complexity, particularly for those programs that wish to pursue the greater-than-150 percent volume target.

Several commenters felt that the proposed measure misaligns 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 it could cause IOTA participants to be more risk averse with the types of organs they accept or disincentivizing IOTA participants from transplanting candidates who have a higher likelihood of graft failure, such as older candidates or those with more comorbid conditions.

[248] *Technical Methods for the Program-Specific Reports.* (n.d.). *www.srtr.org.* Retrieved December 3, 2022, from *https://www.srtr.org/about-the-data/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.*

[249] *Technical Methods for the Program-Specific Reports.* (n.d.). *www.srtr.org.* Retrieved December 3, 2022, from *https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/.*

[250] *https://unos.org/wp-content/uploads/Adult-TRF-Kidney.pdf.*

[251] Zhang, R. (2017). Donor-Specific Antibodies in Kidney Transplant Recipients. *Clinical Journal of the American Society of Nephrology, 13*(1), 182–192. *https://doi.org/10.2215/cjn.00700117.*

Some commenters suggested specific donor and recipient characteristics that CMS should risk adjust for when calculating the proposed composite graft survival rate. For example, a commenter recommended that CMS risk adjust for how sick the patient is or the health of the kidney. Another commenter urged CMS to use SRTR's risk adjustment methodology, as it undergoes regular testing and is updated annually. This commenter also stated that the current SRTR model recommends adjusting for both donor and recipient characteristics, including (1) donor and recipient demographic characteristics such as age, gender, and race, (2) donor and recipient clinical characteristics such as BMI, past behavior, medication history, and (3) history of certain conditions. A commenter suggested CMS consider risk-adjusting the composite graft rate using age, sex, major comorbidities, and neighborhood disadvantage index or similar (for example, CDC Social Vulnerability Index [252]). Lastly, a commenter appreciated CMS's emphasis on encouraging focus on post-transplant outcomes beyond the one- (and three-) year time horizon that currently receive the most focus. The commenter also broadly supported the proposed rolling composite graft survival metric as a mechanism to do so, and in particular, appreciated the simplicity of the proposed approach. However, they believed that CMS should risk-adjust for at least a small number of variables 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 patients. For example, a model that includes age, ESRD vintage, and diabetes mellitus (y/n) the same commenter felt would leverage currently available data and remain easily measurable and understood.

Response: We appreciate the concerns and suggestions from the commenters. We recognize the importance of providing a risk adjustment methodology, but we disagree with modifying how the composite graft survival rate, as proposed, is calculated for PY 1. As discussed in section III.C.5.e(1)(a) of this final rule, we proposed to include this measure as a checkpoint to safeguard patient outcomes under the IOTA Model and sought to convey the importance of ongoing management to preserve the health of the transplanted graft and the health and quality of life of the attributed patients. As discussed at 89 FR 43536 in the proposed rule, 1-year post-transplant outcomes are markedly stable while long term post-transplant outcomes have historically been unchanged. In addition, research has shown that kidney transplant recipients, on average, experience one-year graft and patient survival rates above 95 percent.[253] As such, we believe the composite graft survival rate measure, as proposed, will reflect that for PY 1. We also maintain our belief that this measure would build upon, and complement, existing OPTN and SRTR measures to the maximum extent possible and enhance patient understanding of clinically important post-transplant outcomes beyond existing 90-day, 1-year and 3-year post transplant outcomes.

In light of commenters suggestions, we considered finalizing a risk adjustment methodology that adjusted for donor age, recipient age and recipient diabetes. However, we do not believe that adjusting for these three alone are appropriate. Organ availability is affecting the kidney transplantation in its entirety, leading to transplant teams expanding the criteria for accepting organ donors. 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, we want to make sure that we continue discussions to ensure that this measure eventually includes a robust and appropriate risk adjustment methodology. Furthermore, we believe that the lack of risk adjustment for PY 1 will be minimal in terms of impacting IOTA participants scores and note that IOTA participants would not owe a downside risk payment in PY 1, as described and finalized in section III.C.6 of this final rule.

Therefore, we will be finalizing our composite graft survival methodology, as proposed, to calculate post-transplant outcomes in the IOTA Model. However, in light of comments received, we will be stratifying the data from the composite graft survival rate measure and will work with stakeholders to inform a risk adjustment methodology for this measure and intend to address a new or updated policy pursuant to future notice and comment rule making. We also note that since we are not finalizing our proposed quality measure set or quality measure set scoring methodology, as described in sections III.C.5.e(2) and III.C.5.e(2)(e) of this final rule, and based on public comment, we will be modifying our proposed points allocation. We direct readers to section III.C.5.e(1)(b) for further discussion on the points allocation for the composite graft survival rate measure.

Comment: Several commenters expressed concern over the proposed composite graft survival rate outcome measure. In particular, some commenters felt that the measure contradicts the primary objective of the IOTA Model, which is to increase the number of kidney transplants performed. For instance, a commenter believed that because this proposed measure would evaluate post-transplant outcomes during the IOTA Model performance period that the added requirement to provide six-year data detracts from what should be an unerring and resolute focus on increasing transplant volumes. A commenter also urged CMS to modify or remove this measure from the model in order for the model to succeed in achieving its primary objective. A couple commenters argued that this proposed measure would deter IOTA participants from transplanting lower-quality organs, which are significantly less likely to maintain function for six years post-transplant. Therefore, the commenters felt that the proposed outcome measure is inconsistent with the main objectives of the IOTA Model.

Some commenters also shared that they felt collecting the data required for the proposed composite graft survival rate metric would add additional administrative burden for IOTA participants. Specifically, a commenter suggested that finalizing this measure as proposed would significantly increase the data collection burden on participating transplant programs, as no existing database contains six-year post-transplant graft function data. A commenter also argued that the proposed six-year outcome measure conflicts with the existing monitoring and reporting framework, and introducing a significant unfunded change would be illogical, as it is incongruent with the model's strategic goals. A few commenters felt that this measure, as proposed, increases the time horizon for post-transplant graft survival accountability for transplant

[252] *CDC/ATSDR Social Vulnerability Index (CDC/ATSDR SVI).* (2024, June 14). *cdc.gov. https://www.atsdr.cdc.gov/placeandhealth/svi/index.html.*

[253] Poggio, E.D., Augustine, J.J., Arrigain, S., Brennan, D.C., & Schold, J.D. (2021). Long-term kidney transplant graft survival—Making progress when most needed. *American Journal of Transplantation, 21*(8). *https://doi.org/10.1111/ajt.16463;* Meier-Kriesche, H.U., Schold, J.D., & Kaplan, B. (2004). Long-Term Renal Allograft Survival: Have we Made Significant Progress or is it Time to Rethink our Analytic and Therapeutic Strategies? *American Journal of Transplantation, 4*(8), 1289–1295. *https://doi.org/10.1111/j.1600-6143.2004.00515.x.*

programs that participate. They noted that after the first-year post-transplant, the recipient's nephrologist, rather than the transplant facility, is primarily responsible for the patient's ongoing care. Thus, they felt the six-year timeline was unreasonable, as it would hold transplant programs accountable for ensuring graft function long after the period for which they can be held responsible.

Response: We thank commenters for their input and acknowledge their recommendations and concerns around the proposed composite graft survival rate. As mentioned in comment responses noted previously in this section, we will be finalizing the composite graft survival rate as proposed. However, we will take these insights and recommendations into consideration as we continue to assess our composite graft survival rate measure methodology and, if warranted, will propose a new or updated policy through future notice and comment rulemaking. We also note that in light of comments received, we intend to incorporate a risk adjustment methodology into our proposed approach for calculating post-transplant outcomes in the IOTA Model in future notice and comment rulemaking.

Comment: Several commenters expressed support for using the unadjusted composite graft survival rate as proposed.

Response: We thank the commenters for their support. We direct readers to section III.C.5.e(1)(a) of this final rule for the full discussion of the comments received in support of our proposed composite graft survival rate measure.

After consideration of the public comments received, for the reasons set forth in this rule, we are finalizing the proposed provisions for calculating the composite graft survival rate as proposed at § 512.428(b)(1), without modification. While we are finalizing our provision for calculating the composite graft survival rate as proposed, we will be stratifying the data from the composite graft survival rate measure to inform a risk adjustment methodology for this measure and may consider future notice and comment rulemaking on this topic.

(b) Calculation of Points

As described in section III.C.5.e of the proposed rule, performance on the quality domain would be worth up to 20 points. Within the quality domain, we proposed that the composite graft survival rate would account for 10 of the 20 allocated points. We proposed that the points earned would be based on the IOTA participants' performance on the composite graft survival rate metric ranked against a national target, inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants. We believe that using percentiles would create even buckets of scores among the continuum of IOTA participants.

We proposed that points would be awarded based on the national quintiles, as outlined in Table 8, such that IOTA participants that perform—

- At or above the 80th percentile would earn 10 points;
- In the 60th percentile to below the 80th percentile would earn 8 points;
- In the 40th to below the 60th percentile would earn 5 points;
- In the 20th percentile to below the 40th percentile would earn 3 points; and
- Below the 20th percentile would receive no points for the composite graft survival rate.

TABLE 8: COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance Relative to Target	Points Earned
80^{th} Percentile $\leq$	10
$60^{th} \leq$ and $< 80^{th}$ Percentile	8
$40^{th} \leq$ and $< 60^{th}$ Percentile	5
$20^{th} \leq$ and $< 40^{th}$ Percentile	3
$< 20^{th}$ Percentile	0

Utilizing quintiles aligns with the calculation of the upside and downside risk payments in relation to the final performance score as detailed and finalized in section III.C.6.c(2) of this final rule, where average performance yields half the number of points. The scoring is normalized, meaning an average performing IOTA participant earns 5 points out of 10, or about 50 percent of possible points. We recognize that there is an upper limit to the benefits of efficiency, and quintiles combine the highest 20 percent of performers in a point band. Due to the current disparity among kidney transplant hospitals, we do not expect every IOTA participant to reach top-level performance on this metric.

We considered a strategy similar to the proposed organ offer acceptance methodology which would apply 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. We also considered proposing just an improvement score, in which we would evaluate IOTA participants' performance on composite graft survival during a PY relative to their performance the previous CY. We considered both approaches because we recognize that if an IOTA participant does not do well one year in our proposed methodology, that it may be difficult for it to improve during the model performance period. However, we chose not to propose either of these other methodologies (achievement and improvement or just improvement scoring) because we had concerns over our ability to measure improvement year over year due to potentially small numbers.

We sought public comment on the proposed point allocation and calculation methodology for post-transplant outcomes within the quality domain for the IOTA Model and alternatives considered.

The following is a summary of the comments received on our proposed point allocation and calculation methodology for post-transplant outcomes within the quality domain for the IOTA Model and our responses:

Comment: A few commenters expressed concern over the proposed points allocation. Specifically, a commenter indicated that, despite performing as expected on one-year outcomes, they would receive zero points based on the proposed points allocation, as the observed survival is

ranked low. The commenter attributed this to the transplant hospitals willingness to take on riskier waitlist patients and accept donors that other transplant hospitals may otherwise not. A commenter expressed concern that a small number of adverse scores could significantly skew a transplant hospital's data. They argued that with the relatively low volume of transplants, just a few outlier scores could make it challenging to draw meaningful conclusions or implement impactful changes. As a result, the commenter believed these widely used quality metrics were better suited for evaluating large patient populations, such as in primary care settings. Lastly, a commenter also recommended that CMS adjust the eligibility to obtain maximum points downward in the composite graft survival rate points allocation. Specifically, the commenter suggested that full points be awarded to IOTA participants at the 60th percentile and above instead of the proposed 80th percentile and above.

Response: We thank the commenters for raising concerns around the potential difficulties IOTA participants may face in achieving a top score on the composite graft survival rate metric. Regarding the concerns that a small number of adverse scores could significantly skew a transplant hospital's data, we believe that is difficult for us to approach with so little data. 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. Additionally, we acknowledge that IOTA participants will need time to establish relationships with IOTA collaborators, as described and finalized in section III.C.11.c of this final rule, and we want to allow time for those to be established.

Thus, given this myriad of issues, and in light of public comment, we are finalizing an alternate scoring system for PY 1. Points will be awarded based on the national quintiles, as outlined in Table 9, 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 9: COMPOSITE GRAFT SURVIVAL RATE SCORING

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

We recognize that for PY 2 and future PYs there will be more events and a longer time horizon and plan to implement a more robust methodology that can account for both the likelihood of graft failure based on the donor and the recipient and can account for relative benefits of transplantation over remaining on dialysis. We will 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.

Comment: A commenter expressed support for the proposed point allocation and calculation methodology for post-transplant outcomes within the quality domain for the IOTA Model.

Response: We thank the commenter for their support. As mentioned in comment responses noted previously, since we are not finalizing our proposed quality measure set or quality measure set scoring methodology, as described in sections III.C.5.e(2) and III.C.5.e(2)(e) of this final rule, and based on public comment, we will be modifying our proposed points allocation, as illustrated in Table 9 in this section. We will 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 and provide further specification based on commenters suggestions, if warranted.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed composite graft survival rate scoring methodology within the quality domain at § 512.428(d), as proposed with minor technical corrections to update language to reflect what we proposed at 89 FR 43518 of the proposed rule. Specifically, at § 512.428(d) we are updating the language to reflect that CMS awards points to the IOTA participant based on the IOTA participant's performance on the composite graft survival rate, as described in paragraph (b)(1) of this section, ranked nationally, inclusive of all eligible kidney transplant hospitals.

We are also finalizing our proposal for the proposed point allocation for post-transplant outcomes within the quality domain for the IOTA Model with slight modifications. In section III.C.5.e(2)(e) of the proposed rule, we proposed that the IOTA participant would receive up to 10 points for performance on our three proposed measures within the quality domain while also noting in the proposed rule at 89 FR 43564, that if we finalized fewer measures, then we proposed to allocate the points accordingly within the remaining measures. We acknowledge that by not finalizing any of the proposed quality measures for inclusion in the quality measure set of the quality domain, as described in section III.C.5.e(2) of this final rule, there is a need to account for

the points that we proposed to allocate to them, as described in section III.C.5.e(2)(e) of the preamble in this final rule. Therefore, we are finalizing our proposal with slight modification in Table 1 to paragraph (d) at our regulation at § 512.428(d) to allot a maximum of 20 points for performance on the composite graft survival rate measure.

Additionally, after consideration of the public comments we received, we are also finalizing, with modification, Table 1 to paragraph (d) at § 512.428(d) to reflect the updated points allocation, 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.

(2) Quality Measure Set

In section III.C.5.e(2) of the proposed rule, we proposed to select and use quality measures to assess IOTA participant performance in the quality domain. Performance on the proposed IOTA Model quality measure set would be used to assess the performance of an IOTA participant on aspects of care that we believe contribute to a holistic and patient-centered journey to receiving a kidney transplant.

In section III.C.5.e(2) of the proposed rule, we proposed the following three measures for inclusion in the IOTA Model quality measure set: (1) CollaboRATE Shared Decision-Making Score (CBE ID:3327), (2) Colorectal Cancer Screening (COL) (CBE ID: 0034), and (3) the 3-Item Care Transition Measure (CTM–3) (CBE ID: 0228).[254] [255] [256] The quality measures that we proposed share common features. We proposed measures that have been or are currently endorsed by the CMS Consensus-Entity (CBE) through the CMS Consensus-Based Process. This ensures that the measures proposed have been assessed against established evaluation criteria of importance, acceptability of measure properties, feasibility, usability, and competing measures.[257] Our proposed measure set is patient-centered, reflecting areas that we have heard from patients are important and for which there is significant variation in performance among transplant hospitals. We proposed measures that would incentivize improvements in care that we would otherwise not expect to improve based on the financial incentives in the model alone. We are also proposing a measure set that would allow us to make a comprehensive assessment of post-transplant outcomes. The composite graft survival rate that we proposed in section III.C.5.e(1) of the proposed rule and this final rule would provide an essential, albeit limited, assessment of the success of a kidney transplant. Finally, we proposed measures that we believe would incentivize improvement in aspects of post-transplant care that are important to patients and modifiable by IOTA participants.

We stated in the proposed rule at section III.C.5.e(2) that on March 2, 2023, Jacobs et al. published *Aligning Quality Measures across CMS—The Universal Foundation,* which describes CMS leadership's vision for a set of foundational quality measures known as the Universal Foundation. This measure set would be used by as many CMS value-based and quality programs as possible, with other measures added based on the population or healthcare setting.[258] CMS selected measures for the Universal Foundation that are meaningful to a broad population, reduce burden by aligning measures, advance equity, support automatic and digital reporting, and have minimal unintended consequences.[259]

We considered only including two measures in the initial quality measure set and pre-measure development because we were concerned about the potential added reporting burden placed on IOTA participants (89 FR 43518). However, we chose to propose three measures and pre-measure development because we want to use them to incentivize and improve patient care. We sought additional feedback on which of the proposed measures have the highest potential to impact changes in behavior, while minimizing provider burden.

We also considered only including COL in the quality measure set and allotting this measure 4 points, with the remaining 16 points allotted to the composite graft survival rate (89 FR 43518). It is worth noting that if we choose fewer measures, then we proposed allocating the points accordingly within the remaining measures.

We considered several alternative measures for the quality domain performance assessment (89 FR 43518). We considered the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey because hospitals are already required to report that survey in the Hospital VBP Program, thereby reducing or limiting burden to IOTA participants burden since it is already in use. We did not propose the HCAHPS measure for the IOTA Model because HCAHPS data is based on survey results from a random sample of adult patients across medical conditions. We believe that the HCAHPS would present sample size issues for purposes of calculation.

We considered the Gains in Patient Activation Measure (PAM®) (CBE ID: 2483) (89 FR 43518). The PAM® measure is being used in the voluntary KCC Model and was included on the 2022 Measures Under Consideration (MUC) List for the ESRD Quality Incentive Program (QIP) and MIPS.[260] We considered whether the PAM® Measure could encourage IOTA participants and IOTA Collaborators, as defined and finalized in section III.C.11.d of this final rule, to activate IOTA waitlist patients to work in collaboration with IOTA participants to complete requirements to maintain active waitlist status; however, we were unable to locate any peer-reviewed literature to support this hypothesis.

As described in section III.C.5.e(2) of the proposed rule, we also considered the Depression Remission at 12 Months measure (CBE ID: 0710e). Studies have shown that depression and anxiety are common amongst people on dialysis and suggested that incorporating patient reported outcome measures (PROs) that

[254] *collaboRATE.* (2019). Glyn Elwyn. *http://www.glynelwyn.com/collaborate.html.*

[255] *Colorectal Cancer Screening—NCQA.* (2018). NCQA. *https://www.ncqa.org/hedis/measures/colorectal-cancer-screening/* https://www.ncqa.org/hedis/measures/colorectal-cancer-screening/.

[256] *THE NATIONAL QUALITY FORUM Specifications for the Three-Item Care Transition Measure—CTM–3.* (n.d.). Retrieved May 28, 2023, from *https://mhdo.maine.gov/_pdf/NQF_CTM_3_%20Specs_FINAL.pdf.*

[257] Supplemental Material to the CMS Measures Management System (MMS) Hub CMS Consensus-Based Entity (CBE) Endorsement and Maintenance. (2022). *https://www.cms.gov/files/document/blueprint-nqf-endorsement-maintenance.pdf.*

[258] Jacobs, D.B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the Universal Foundation. *New England Journal of Medicine, 388*(9), 776–779. *https://doi.org/10.1056/nejmp2215539.*

[259] Jacobs, D.B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the Universal Foundation. *New England Journal of Medicine, 388*(9), 776–779. *https://doi.org/10.1056/nejmp2215539.*

[260] *Pre-Rulemaking | The Measures Management System.* (n.d.). *Mmshub.cms.gov.* Retrieved May 12, 2023, from *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/overview.*

focus on depression can improve health-related quality of life in patients with ESRD.[261] One study found that, at the time of kidney evaluation, over 85 percent of patients exhibited at least minimal depressive symptoms and that patients with depressive symptoms were less likely to gain access to the waitlist.[262] Although the waitlist offers some hope to patients, being waitlisted for a kidney transplant is also psychologically distressing, with patients reporting disillusionment, moral distress, unmet expectations, increasing vulnerability, and deprivation.[263] These factors are likely contributors to high rates of stress and anxiety observed among waitlisted patients.[264] The conditions of participation (CoPs) for transplant hospitals require that prospective transplant candidates receive a psychosocial evaluation prior to placement on a waitlist (42 CFR 482.90(a)(1)), if possible, and OPTN bylaws specify that transplant hospitals must include team members to coordinate a transplant candidate's psychosocial needs; however, neither the CoP nor the OPTN bylaws require specific assessment of, or intervention into, patients' behavioral health. The ESRD QIP measure set includes the Clinical Depression Screening and Follow-Up measure; however, performance on the measure requires only documentation that an attempt at screening and follow up was made.[265] Additionally, this measure is already being used in the KCC Model.

We stated in the proposed rule that while we understand the importance of including measures focused on depression, we believe that IOTA participants may have limited experience diagnosing and treating depression and may struggle to make referrals due to limited behavioral health providers (89 FR 43518). We also believe that this measure may be duplicative with other policies in this model that strive to improve the health and post-transplant outcomes of attributed patients. Additionally, based on the KCC Model experience, the Depression Remission measure is operationally complex due to the 10-month reporting period and novel collection and reporting processes. We believe that IOTA participants would experience similar challenges due to the mandatory nature of the model and unfamiliarity with reporting quality measure data to the Innovation Center.

In section III.C.5.e(2) of the proposed rule, we considered the Depression Remission at 12 Months measure (CBE ID: 0710e) because major depression is prevalent in the dialysis population and most kidney transplant recipients spend some time on a dialysis modality.[266] Depression measures are included in the Universal Foundation because successfully treating depression can improve physical health outcomes, in addition to behavioral health outcomes.[267] A depression measure would align with the behavioral health domain of Meaningful Measures 2.0. We considered a depression remission measure over a depression screening measure because we believed a depression remission measure would incentivize IOTA participants to work with the other clinicians and providers involved in the care of attributed patients to resolve or improve the depressive symptoms rather than only identifying them. Our review of the literature found that presence of behavioral health symptoms affected the ability of patients to get on the kidney transplant waiting list, but did not affect likelihood of receiving a kidney transplant.[268] We did not propose the Depression Remission at 12 Months Measure because we were unable to locate any publications that found depression remission affected access to a kidney transplant. We also chose not to propose this type of measure because the IOTA Model does not target pre-waitlist patients for attribution to model participants. We also believe that IOTA participants may have limited experience in diagnosis and treating depression and may struggle to make referrals due to limited behavioral health providers. Additionally, behavioral health management is not under the purview of a kidney transplant hospital that might see a kidney transplant waitlist patient perhaps only a handful of times, but may be more appropriate for the patient's nephrologist or dialysis center.

We sought comment on our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) for purposes of measuring performance in the quality domain. We also sought comment on alternative quality measures considered.

The following is a summary of the comments received on our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) for purposes of measuring performance in the quality domain and alternative quality measures considered and our responses:

Comment: We received many responses from commenters who did not agree with the proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening), as described in the preamble of this final rule, in the IOTA Model and highlight several reasons. Commenters stated that the proposed measures have not been

[261] Feroze, U., Martin, D., Kalantar-Zadeh, K., Kim, J.C., Reina-Patton, A., & Kopple, J.D. (2012). Anxiety and depression in maintenance dialysis patients: Preliminary data of a cross-sectional study and brief literature review. *Journal of Renal Nutrition, 22*(1), 207–210. *https://doi.org/10.1053/j.jrn.2011.10.009;* Mclaren, S., Jhamb, M., & Unruh, M. (2021). Using Patient-Reported Measures to Improve Outcomes in Kidney Disease. *Blood Purification,* 1–6. *https://doi.org/10.1159/000515640;* Cukor, D., Donahue, S., Tummalapalli, S.L., Bohmart, A., & Silberzweig, J. (2022). Anxiety, comorbid depression, and dialysis symptom burden. *Clinical Journal of the American Society of Nephrology, 17*(8), 1216–1217. *https://doi.org/10.2215/cjn.01210122.*

[262] Chen, X., Chu, N.M., Basyal, P.S., Vihokrut, W., Crews, D., Brennan, D.C., Andrews, S.R., Vannorsdall, T.D., Segev, D.L., & McAdams-DeMarco, M.A. (2022). Depressive symptoms at kidney transplant evaluation and access to the kidney transplant waitlist. *Kidney International Reports, 7*(6), 1306–1317. *https://doi.org/10.1016/j.ekir.2022.03.008.*

[263] 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.*

[264] Ibid.

[265] *CMS ESRD Measures Manual for the 2023 Performance Period.* (2022). *https://www.cms.gov/files/document/esrd-measures-manual-v81.pdf.*

[266] Cukor, D., Donahue, S., Tummalapalli, S.L., Bohmart, A., & Silberzweig, J. (2022). Anxiety, comorbid depression, and dialysis symptom burden. *Clinical Journal of the American Society of Nephrology, 17*(8), 1216–1217. *https://doi.org/10.2215/cjn.01210122.*

[267] Jacobs, D.B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the Universal Foundation. *New England Journal of Medicine, 388*(9), 776–779. *https://doi.org/10.1056/nejmp2215539.*

[268] Szeifert, L., Bragg-Gresham, J.L., Thumma, J., Gillespie, B.W., Mucsi, I., Robinson, B.M., Pisoni, R.L., Disney, A., Combe, C., & Port, F.K. (2011). Psychosocial variables are associated with being wait-listed, but not with receiving a kidney transplant in the dialysis outcomes and Practice Patterns Study (dopps). *Nephrology Dialysis Transplantation, 27*(5), 2107–2113. *https://doi.org/10.1093/ndt/gfr568;* Chen, X., Chu, N.M., Basyal, P.S., Vihokrut, W., Crews, D., Brennan, D.C., Andrews, S.R., Vannorsdall, T.D., Segev, D.L., & McAdams-DeMarco, M.A. (2022). Depressive symptoms at kidney transplant evaluation and access to the kidney transplant waitlist. *Kidney International Reports, 7*(6), 1306–1317. *https://doi.org/10.1016/j.ekir.2022.03.008.*

developed, validated, or evaluated for use in this patient population and expressed uncertainty to how effective they would be in the model. A few commenters noted that the CollaboRATE Shared Decision-Making measure and CTM–3 are not currently being utilized by transplant hospitals and lack any evidence base for use in kidney transplantation or in patients with CKD and ESRD. Thus, including PRO–PMs without any convincing evidence base for efficacy could be counterproductive and discourage support for PRO measurements generally. Additionally, because the proposed quality measures are not currently used in any CMS program, a commenter anticipated that IOTA participants would face additional costs to implement these new requirements.

Response: We thank commenters for expressing their concerns with the proposed quality measures. While we recognize that the CollaboRATE measure, COL and CTM–3 are not specific to transplantation, we believe they are helpful measures for assessing hospital quality and performance for the reasons set forth in sections III.C.5.e(2)(b), (c), and (d) of this final rule. However, in response to public comments, we will not be finalizing our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) at this time.

Comment: A commenter agreed with the importance of assessing both patient's level of SDM and readiness for self-care at the time of discharge but did not support the use of patient report survey-based measures. The commenter suspected that adding another survey would likely result in low response rates and survey fatigue. Patients are already overwhelmed by the numerous surveys from hospitals, doctors, dialysis centers, and post-acute care providers. Additionally, the commenter argued that transplant patients, who already face significant demands on their time and energy, would likely not prioritize completing survey measures.

Response: We appreciate the commenters' concerns regarding the use of patient-report survey measures, but we disagree. Chronic kidney disease is complex and demands thorough medical management, even after transplantation. Thus, when taking into consideration the lasting impact of CKD, symptom burden and its correlation to mental health and psychosocial difficulties, we believe it is essential that we understand the entirety of the patient experience and take steps to improve it using the policy levers available in the IOTA Model. We maintain that failure to address what is important to patients could result in continued, or the development of, decreased quality of life in addition to psychosocial distress, increased symptom burden and new physical problems or both to arise and be left untreated. We also acknowledge that it is equally important that any PROM included be relevant to the population being measured. To date, there are not only no kidney transplant specific PROs that are endorsed by NQF but there also remains a shortage of kidney transplant specific validated measures. However, given commenters concerns, we are persuaded not to finalize our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) at this time. We still believe in the importance of using validated, person-centered, measures of quality of care to support a holistic and patient-centered kidney transplant process, but acknowledge the challenges presented by commenters in the proposed quality measures set. We intend to propose additional quality measures which may include a focus on health-related quality of life (HRQoL) for kidney transplant recipients or address pre-transplant processes of care through future notice and comment rule making. We believe these measures will support the goals of the IOTA Model to improve quality and equity of care. In the interim, we have been convinced the other requirements that enforce SDM in the pre-transplant process (for example, Transplant Hospitals' CoP) are adequate and mitigate the challenges posed by the proposed measures. Although we are not finalizing any of the proposed measures in our quality measure set, we think that the IOTA Model promotes SDM through some of our other policies, such as the proposed transparency requirements as described and finalized in section III.C.8(a) of the preamble in this final rule.

Comment: Some commenters encouraged CMS to include the PAM® in the IOTA Model. A couple commenters noted that while the PAM® is not validated for use in transplantation it would serve as continuity with other models. A few commenters acknowledged that we considered whether the PAM® Measure could encourage IOTA participants and IOTA Collaborators, as defined at § 512.402 of the proposed rule, to activate IOTA waitlist patients to work in collaboration with IOTA participants to complete requirements to maintain active waitlist status; however, we were unable to locate any peer-reviewed literature to support this hypothesis. One of these commenters recommended that CMS reevaluate possible inclusion of the PAM in the IOTA Model quality measure set after the public release of data on the PAM® use in the voluntary KCC Model. While a couple commenters disagreed with CMS, suggesting that there was ample evidence to support the inclusion of PAM® in the IOTA Model. Specifically, they asserted that the PAM® is well established, in use, valid and reliable across the kidney care journey, including specific peer reviewed studies on the proposed IOTA population. Moreover, they asserted that the evidence demonstrates the crucial importance of patient activation for patients diagnosed with CKD, particularly within the transplant population. Furthermore, the findings suggest that clinical teams could have a profound impact on supporting the main objectives of the IOTA Model.

Response: We appreciate the suggestion from commenters to include the PAM® in the IOTA Model and will consider the suggestion for future rulemaking, where appropriate. Given the concerns raised by commenters about participant burden associated with PRO–PMs, including PAM®, we are not proposing to add it at this time. Rather, as mentioned in comment responses noted previously, we will consider future PRO–PMs use in the model.

Comment: Many commenters suggested alternative measures that the IOTA Model should include in place of those proposed quality measure set. For example, a commenter recommended that CMS consider implementing stronger quality protections during the first two years of the model; suggesting that this could include assessing performance on additional process measures that reflect appropriate care delivery, rather than relying solely on pay-for-reporting. To align with the updates to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, a commenter suggested that CMS should replace the retired CTM–3 measure with the proposed ''Care Coordination'' Sub-Measure.

Several commenters suggested that CMS include more specific health screening measures in place of the COL. For example, a commenter stated that colon cancer rates are similar between kidney transplant and non-transplant patients. Whereas skin cancer has a much higher prevalence in transplant

patients compared to non-transplant patients. Thus, they suggested that there would be more value in creating a skin cancer measure. The commenter also mentioned that they contemplated suggesting that CMS consider using a vaccination rate measure in place of the COL, since being current on vaccinations is more directly relevant to transplant candidate readiness and transplant recipient well-being regardless of age than colorectal cancer screening. However, they suggested that vaccination rates could present an evolving challenge for IOTA participants to achieve given the growing skepticism of vaccinations in the post-COVID–19 pandemic era. The same commenter also believed that many programs exclude individuals who refuse vaccinations who would otherwise be good transplant candidates, and such a metric could further encourage the exclusion of these patients. A couple of commenters suggested that addressing post-transplant cardiovascular risk factors could lead to better long-term outcomes. This is because multiple adverse cardiac events are more common causes of death than cancer or infection after transplant, noting that nearly 25 percent of deaths in the first-year post-transplant are related to cardiovascular reasons. Therefore, the commenters recommended that CMS include measures to screen for post-transplant diabetes mellitus and manage hyperlipidemia.

A few commenters mentioned that CMS should include the Hemoglobin A1c poor control (≤9%) (CBE #0559) and Advance Care Plan (CBE #0326) measures to the quality domain to align with the Universal Measures. A commenter suggested that the Advance Care Plan and CollaboRATE score align with the program's other measures, collectively upholding a high standard of care for transplant patients. Specifically, the commenter proposed that the Advance Care Plan and CollaboRATE score could work together to facilitate a comprehensive, patient-informed decision-making process. Another commenter encouraged CMS to consider the 15-item Care Transition Measure (CTM–15), proposing that it could facilitate a better understanding of post-transplant expectations for patients due to its incorporation of components like a written care plan and a list of scheduled appointments.

Response: We would like to thank all commenters that closely reviewed and shared their suggestions for with the IOTA Model proposed quality measures, and recognize the efforts made by commenters to align measures relevant to the target population and to align to the Universal Foundation, a key CMS priority. We are committed to including quality measures in the IOTA quality domain to further the model goals for improving quality of care and supporting a holistic, patient-centered kidney transplant process. Responsive to comments, we will not be finalizing our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening). We will consider future measures aligned to the priority areas of the kidney transplant process and will align, where possible, with CMS priorities and other CMS programs.

Comment: Numerous commenters expressed concerns about the proposed quality measure reporting requirements. They cited challenges with data collection, administrative burden, and unfamiliarity with the measures; ultimately suggesting that the data collected would not justify the added administrative burden. For example, a commenter stated that if patients are attributed to multiple transplant hospitals, collecting quality measures data on the entire attributed population could be duplicative and burdensome. The same commenter also believed that allowing for quality measures to change each PY that it would cause confusion and lost revenue, and that more consideration should be put into the process for data collections so that it does not unduly burden programs in a way that compromises clinical outcomes and organ transplant access. A commenter stated that SDM and patient involvement in transplant care, as well as patient autonomy, are respected and assessed in the evaluation process but do not directly support the goal of improving patient outcomes. Thus, they felt that the that administering the CollaboRATE Shared Decision-Making Score and CTM–3 would cause unnecessary administrative burden. Another commenter expressed their belief that administering and documenting the CollaboRATE Shared Decision-Making Score and CTM–3 would be laborious due to the volume of patients on the waitlist and questioned how this would be accomplished in a consistent manner.

Response: We appreciate and acknowledge the commenters' concern and challenges with the proposed quality measures. We recognize the difficulties associated with patient reported outcome measures and the underlying data collection tools used in a clinical domain. At this point, as mentioned in comment responses noted previously, we are not finalizing any of the three quality measures that we proposed. In the future we plan to propose additional quality measures which may include a focus on HRQoL for kidney transplant recipients or address pre-transplant processes of care. We suggest these measures would support the goals of the IOTA Model to improve quality and equity of care and acknowledge the burden of data collection in measures using EHR or survey data. However, it is a CMS priority to incorporate person-centered measures, including patient-reported measures, where possible. We will continue to consider EHR reporting challenges when selecting quality measures to account for future performance and intends to propose new quality measures for inclusion in the IOTA Model through future notice and comment rulemaking.

Comment: A few commenters supported the inclusion of patient-reported outcome (PRO) measures in the IOTA Model. For example, a commenter believed that including PROs is essential for evaluating the quality of care and patient satisfaction but believed that the quality measure set scoring methodology, as described at § 512.428(e) of the proposed rule could inaccurately reflect the quality of care or patient satisfaction and lacked transparency and consistency; suggesting that it could cause discrepancies in evaluating IOTA participant performance. A commenter strongly supported the use of quality measures to evaluate transparency and SDM. This commenter also voiced their belief that the proposed quality measure was good because it did not significantly increase administrative burden but thought the measures' simplicity might limit their ability to provide meaningful insights into the quality of care these patients receive. Another commenter voiced their appreciation for CMS's inclusion of PROMs in the IOTA Model. The same commenter agreed that increasing patient involvement in the kidney transplant process is a critical objective but expressed concern over the inclusion of CollaboRATE and CTM–3. Specifically, the commenter felt that administering and documenting these measures, which have not been validated for this specific patient population, would increase burden on both IOTA participants and its attributed patients, without improving quality of care.

Response: We thank the commenters for expressing their support. We agree that when taking into consideration the lasting impact of CKD, symptom

burden, and its correlation to mental health and psychosocial difficulties, it is important that the patient perspective and voice be included through the use of patient-reported outcome measures (PROMs) to truly grasp how CKD impacts their lives.[269] As described at 89 FR 43603 in the proposed rule, we also recognize that in spite of the growing recognition over the past two decades that this is paramount to advancing the quality of care at both the patient and policy levels, there remains significant information gaps in understanding how PROMs are, and can be utilized across different domains, especially within nephrology to enrich patient-centered care, and measure other important quality components, such as access to transplantation, shared-decision making and quality of life post-transplantation, to provide a comprehensive understanding.[270] However, given commenters concerns, we are persuaded not to finalize the three quality measures proposed for inclusion in the IOTA Model at this time. It is a CMS priority to incorporate person-centered measures, including patient-reported measures, where possible and CMS believes in the importance of elevating patient's voice in their care. We plan, in future notice and comment rulemaking, to propose additional quality measures which may include a focus on HRQoL for kidney transplant recipients or address pre-transplant processes of care. We suggest these measures will support the goals of the IOTA Model to improve quality and equity of care.

Comment: Lastly, many commenters urged CMS to focus on new measure development and collaborate with stakeholders, clinicians, and patients to develop meaningful quality measures in this space that can be validated in this setting. For example, many commenters encouraged CMS to eliminate the proposed quality measure and pursue new measure development. These commenters also stated that it is critical that CMS include all relevant stakeholders when developing new measures to ensure that any new measure is appropriate, reliable, and representative of the diverse patient population. A commenter appreciated CMS's interest in developing a PROM pertaining to HRQoL in the context of kidney transplant especially given the relative paucity of measures of quality of care for kidney transplant; nothing that no validated PROMs of quality of life currently exist, much less any PROMs that are appropriate for use in the IOTA Model. A commenter strongly supported the development of a HRQoL PROM and suggested CMS invest in developing a measure(s) along these lines for inclusion in the IOTA Model as soon as possible. Some commenters voiced their belief that CMS should work with relevant stakeholders and focus on, and invest, in new measure development, provided it is rigorously tested and developed using the highest standards. One of these commenters suggested that it be used as a reporting measure initially before rewarding performance against quality performance benchmarks and should assess SDM about patient-focused risk tolerance regarding organ offer quality.

Response: We acknowledge commenters suggestions for CMS to focus on new measure development for use in the IOTA Model, including support for a future PROM related to HRQoL for kidney transplant recipients. Appropriately evaluating the change in quality of care is an essential goal of the IOTA Model and we will consider future measure development, potentially in the areas of HRQoL and pre-transplant processes of care.

After considering public comments, for the reasons set forth in this rule, we are not finalizing our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) for purposes of measuring performance in the quality domain at this time. We continue to note that quality of care is an important element of the IOTA Model, and we will be monitoring quality through other care delivery requirements and through the required independent evaluation of the model. We also will continue to evaluate the changing inventory of quality measures, considering public input, and have already begun developing new measures more clinically and setting appropriate. Because of the uncertain nature of timing of developing new quality measures we will not specify a timeline for incorporation but may in future rulemaking.

(a) Quality Measure Set Selection, Reporting and Changes

In section III.C.5.e(2) of the proposed rule, we proposed that CMS select and use quality measures to assess IOTA participant performance in the quality domain. We proposed that each PY, IOTA participants would be required to report quality measure data during survey and reporting windows to CMS in a form and manner, and at times, established by CMS. We also proposed that, where applicable, IOTA participants would be required to administer any surveys or screenings relevant to the quality measures selected for inclusion in the IOTA Model to attributed patients. We proposed to define ''survey and reporting windows'' as two distinct periods where IOTA participants would be required to administer a quality measure-related survey or screening to attributed patients or submit attributed patient responses to CMS pursuant to § 512.48(b)(2)(ii). We proposed that CMS would notify, in a form and manner as determined by CMS, IOTA participants of the survey and reporting window for applicable quality measures by the first day of each PY.

In section III.C.5.e(2)(a) of the proposed rule, we proposed that CMS would use future rulemaking to make substantiative updates to the specifications of any of the quality measures in the IOTA Model. Additionally, we proposed that the quality measures finalized for inclusion in the IOTA Model would remain in the quality measure set unless CMS, through future rulemaking, removed or replaced them.

In section III.C.5.e(2)(a) of the proposed rule, we proposed that CMS could remove or replace a quality measure based on one of the following factors:

- A quality measure does not align with current clinical guidelines or practice.
- Performance on a quality measure among IOTA participants is so high and unvarying that meaningful distinctions

[269] Schick-Makaroff, K., Thummapol, O., Thompson, S., Flynn, R., Karimi-Dehkordi, M., Klarenbach, S., Sawatzky, R., & Greenhalgh, J. (2019). Strategies for incorporating patient-reported outcomes in the care of people with chronic kidney disease (PRO kidney): a protocol for a realist synthesis. *Systematic Reviews, 8*(1). *https://doi.org/10.1186/s13643-018-0911-6;* Brett, K.E., Ritchie, L.J., Ertel, E., Bennett, A., & Knoll, G.A. (2018). Quality Metrics in Solid Organ Transplantation. *Transplantation, 102*(7), e308–e330. *https://doi.org/10.1097/tp.0000000000002149;* Mendu, M.L., Tummalapalli, S.L., Lentine, K.L., Erickson, K.F., Lew, S.Q., Liu, F., Gould, E., Somers, M., Garimella, P.S., O'Neil, T., White, D.L., Meyer, R., Bieber, S.D., & Weiner, D.E. (2020). Measuring Quality in Kidney Care: An Evaluation of Existing Quality Metrics and Approach to Facilitating Improvements in Care Delivery. *Journal of the American Society of Nephrology, 31*(3), 602–614. *https://doi.org/10.1681/ASN.2019090869;* Tang, E., Bansal, A., Novak, M., & Mucsi, I. (2018). Patient-Reported Outcomes in Patients with Chronic Kidney Disease and Kidney Transplant—Part 1. *Frontiers in Medicine, 4. https://doi.org/10.3389/fmed.2017.00254;* Anderson, N.E., Calvert, M., Cockwell, P., Dutton, M., Aiyegbusi, O.L., & Kyte, D. (2018). Using patient-reported outcome measures (PROMs) to promote quality of care in the management of patients with established kidney disease requiring treatment with haemodialysis in the UK (PROM–HD): a qualitative study protocol. *BMJ Open, 8*(10), e021532. *https://doi.org/10.1136/bmjopen-2018-021532.*

[270] Ibid.

and improvement in performance can no longer be made (''topped out'' measure), as defined in 42 CFR 412.140(g)(3)(i)(A).

- Performance or improvement on a quality measure does not result in better patient outcomes.
- The availability of a more broadly applicable quality measure (across settings or populations) or the availability of a quality measure that is more proximal in time to desired patient outcomes for the particular topic.
- The availability of a quality measure that is more strongly associated with desired patient outcomes for the particular topic.
- Collection or public reporting of a quality measure leads to negative unintended consequences other than patient harm.
- It is not feasible to implement the quality measure specifications.
- The costs associated with a quality measure outweigh the benefit of its continued use in the IOTA Model.

In section III.C.5.e(2)(a) of the proposed rule, we proposed that CMS would assess the benefits of removing or replacing a quality measure from the IOTA Model on a case-by-case basis. We proposed that CMS would use the future rulemaking process to add, remove, suspend, or replace quality measures in the IOTA Model to allow for public comment, unless a quality measure raises specific safety concerns. We proposed that if CMS determines that the continued requirement for IOTA participants to submit data on a quality measure raises specific patient safety concerns, CMS could elect to immediately remove the quality measure from the IOTA Model quality measure set. Finally, we proposed that CMS would, upon removal of a quality measure, and in a form and manner determined by CMS, do the following:

- Provide notice to IOTA participants and the public at the time CMS removes the quality measure, along with a statement of the specific patient safety concerns that would be raised if IOTA participants continued to submit data on the quality measure.
- Provide notice of the removal in the **Federal Register**.

We sought comment on the requirement that IOTA participants report quality measure data to CMS. We additionally sought comment on our proposed process for adding, removing, or replacing quality measures in the IOTA Model.

The following is a summary of the comments received on our proposal to require that IOTA participants report quality measure data to CMS and our proposed process for adding, removing, or replacing quality measure in the IOTA Model and our responses:

Comment: Several commenters felt that more consideration should be put into the process for data collection and reporting requirements so that it does not unduly burden IOTA participants in a way that could compromise clinical outcomes and transplant access. A commenter felt that CMS's proposed rule lacked key logistical details necessary to understand how IOTA participants would collect the required quality measures and how CMS would evaluate them. Specifically, the proposed rule did not specify what patient information IOTA participants must collect and report alongside the measure results, nor whether hospitals should provide patient-level or aggregate data.

Response: We understand the need for IOTA participants understand any quality measure set survey and reporting requirements finalized for inclusion in the IOTA Model. Additionally, we acknowledge the importance of, are committed to, providing key logistical details, where warranted, to mitigate administrative burdens for IOTA participants. As discussed in section III.C.5.e(2) of this final rule, we are not finalizing our proposed quality measure set. We intend to propose new quality measures for inclusion in the IOTA Model in future notice and comment rule making. As such, we will not be finalizing our proposed quality measure set survey and reporting requirements at § 512.428(b)(2)(ii), our proposed process for adding, removing or replacing a quality measure at § 512.428(b)(3) or the definition of survey and reporting windows at § 512.402 as described in the proposed rule. While we are not finalizing any of the aforementioned provisions, we will continue to assess our quality measure data reporting requirement and policy for adding, removing, or replacing quality measures in the IOTA Model and intend to address a new or updated policy pursuant to future notice and comment rule making.

Comment: A commenter urged CMS to allow greater flexibility in the proposed survey and reporting timelines, as discussed in section III.C.5.e(2)(a) of this final rule, for IOTA participants and recommended that CMS allow IOTA participants to adjust data collection processes to align with clinical schedules and patient preference. They noted that by allowing for greater flexibility that this would enable them to collect patient data in alignment with clinical practice for pre- and post-transplant appointments and prevent potential operational challenges if or when a survey and reporting window misaligns.

Response: We appreciate the commenters' suggestion. As discussed in section III.C.5.e(2) of this final rule, we are not finalizing our proposed quality measure set. We intend to propose new quality measures for inclusion in the IOTA Model in future notice and comment rule making. As such, we will not be finalizing our proposed quality measure set survey and reporting requirements at § 512.428(b)(2)(ii), our proposed process for adding, removing or replacing a quality measure at § 512.428(b)(3) or the definition of survey and reporting windows at § 512.402 as described in the proposed rule. While we are not finalizing any of the provisions proposed in section III.C.5.e(2) of the proposed rule, we will take into consideration the commenter's recommendation to allow for greater flexibility during survey and reporting windows and continue to assess our quality measure data reporting requirement and policy for adding, removing, or replacing quality measures in the IOTA Model. We note that we will continue to assess our quality measure data reporting requirement and policy for adding, removing, or replacing quality measures in the IOTA Model and intend to address a new or updated policy pursuant to future notice and comment rule making.

Comment: A commenter noted that in the proposed rule we proposed that if performance on a quality measure among IOTA participants is so high and unvarying that meaningful distinctions and improvement in performance can no longer be made (''topped out'' measure), as defined in 42 CFR 412.140(g)(3)(i)(A) that CMS could remove or replace that quality measure (89 FR 43518). They requested that CMS provide further detail on the proposed CMS review process and timeline for evaluating if ''topping out'' or other criteria has occurred. They also felt that while case-by-case adjustments may be appropriate when specific concerns arise, an ad hoc evaluation process risks overlooking instances where quality measures fall short of the established criteria.

Response: We appreciate the commenters' suggestion. As discussed in section III.C.5.e(2) of this final rule, we are not finalizing our proposed quality measure set. We intend to propose new quality measures for inclusion in the IOTA Model in future notice and comment rule making. As such, we will not be finalizing any of the provisions proposed in section

III.C.5.e(2)(a) of the proposed rule. While we are not finalizing any of these proposed provisions, we will take into consideration the commenter's request to provide further specificity to our application of measure removal factors and continue to assess our quality measure data reporting requirement and policy for adding, removing, or replacing quality measures in the IOTA Model.

After consideration of the public comments we received, for the reasons set forth in this rule, we are not finalizing our policy for adding, removing, or replacing quality measures in the IOTA Model, as proposed at § 512.428(b)(2) of the proposed rule. Additionally, because we are not finalizing any of the quality measures we proposed, as described and finalized in section III.C.5.e(2) of this final rule, we are not finalizing our proposed provision requiring IOTA participants to report quality measure data to CMS at § 512.428(b)(2)(ii) or the definition of survey and reporting windows at § 512.402 as described in the proposed rule. While we are not finalizing any of these proposed provisions, we will continue to assess our quality measure data reporting requirement and policy for adding, removing, or replacing quality measures in the IOTA Model and address a new or updated policy pursuant to future notice and comment rule making.

(b) CollaboRATE Shared Decision-Making Score

In section III.C.5.e(2)(b) of the proposed rule, we stated that the CollaboRATE Shared Decision-Making Score is a patient-reported measure of shared decision-making. The measure provides a performance score representing the percentage of adults 18 years of age and older who experience a high degree of shared decision making. The CollaboRATE Shared Decision-Making Score is based on three questions that assess the degree to which effort was made to inform the patient of his or her health issues, to listen to the patient's priorities, and the extent to which the patient's priorities were included in determining next steps. The measure is generic and applies to all clinical encounters, irrespective of the condition or the patient group. We proposed that IOTA participants would be required to administer the CollaboRATE Shared Decision-Making Score to attributed patients once per PY, at minimum, and report quality measure data to CMS during survey and reporting windows, as defined in section III.C.5.e(2)(a) of the proposed rule, that would be established by CMS.

In section III.C.5.e(2)(b) of the proposed, we stated that we believed incentivizing shared decision-making is critical to ensuring the model centers the patient experience and treatment choice to meet the IOTA desired goals of improving equity, increasing the number of kidney transplants, and reducing kidney non-utilization. Patients needing a kidney transplant often face many challenges when making healthcare decisions, as they must first decide between treatment options (such as dialysis versus transplantation, living donor versus deceased-donor transplantation) and where they wish to be evaluated for transplantation. Research findings demonstrate the importance and impact of shared decision-making throughout the entire transplant process for patients because of the types of complex decisions they must make, and the dynamic factors involved in each patient's decision.[271] Research studies have found that shared decision-making shifts the patient-physician relationship past traditional practices and contributes to better health outcomes, increased quality of life, increased patient knowledge and medication adherence, and lower healthcare expenditures.[272] Furthermore, research findings support that shared decision-making with the patient could reduce kidney non-utilization, improve equity, and increase the number of kidney transplants.[273]

[271] Jones, E.L., Shakespeare, K., McLaughlin, L., & Noyes, J. (2023). Understanding people's decisions when choosing or declining a kidney transplant: a qualitative evidence synthesis. BMJ Open, 13(8), e071348. *https://doi.org/10.1136/bmjopen-2022-071348;* Stephenson, M.D., & Bradshaw, W. (2018). Shared decision making in chronic kidney disease. *Renal Society of Australasia Journal, 14*(1), 26. *https://www.proquest.com/scholarly-journals/shared-decision-making-chronic-kidney-disease/docview/2283078287/se-2;* Gordon, E.J., Butt, Z., Jensen, S.E., Lok-Ming Lehr, A., Franklin, J., Becker, Y., Sherman, L., Chon, W.J., Beauvais, N., Hanneman, J., Penrod, D., Ison, M.G., & Abecassis, M.M. (2013). Opportunities for Shared Decision Making in Kidney Transplantation. American Journal of Transplantation, 13(5), 1149–1158. *https://doi.org/10.1111/ajt.12195;* Salter, M.L., Babak Orandi, McAdams-DeMarco, M.A., Law, A., Meoni, L.A., Jaar, B.G., Sozio, S.M., Hong, W., Parekh, R.S., & Segev, D.L. (2014). Patient- and Provider-Reported Information about Transplantation and Subsequent Waitlisting. Journal of the American Society of Nephrology, 25(12), 2871–2877. *https://doi.org/10.1681/asn.2013121298;* Schold, J.D., Huml, A.M., Poggio, E.D., Reese, P.P., & Mohan, S. (2022). A tool for decision-making in kidney transplant candidates with poor prognosis to receive deceased donor transplantation in the United States. Kidney International. *https://doi.org/10.1016/j.kint.2022.05.025;* Schaffhausen, C.R., Bruin, M.J., McKinney, W.T., Snyder, J.J., Matas, A.J., Kasiske, B.L., & Israni, A.K. (2019). How patients choose kidney transplant centers: A qualitative study of patient experiences. 33(5), e13523–e13523. *https://doi.org/10.1111/ctr.13523;* Hart, A., Bruin, M., Chu, S., Matas, A., Partin, M.R., & Israni, A.K. (2019). Decision support needs of kidney transplant candidates regarding the deceased donor waiting list: A qualitative study and conceptual framework. Clinical Transplantation, 33(5), e13530. *https://doi.org/10.1111/ctr.13530;* S. Ali Husain, Brennan, C., Michelson, A., Tsapepas, D., Patzer, R.E., Schold, J.D., & Mohan, S. (2018). Patients prioritize waitlist over posttransplant outcomes when evaluating kidney transplant centers. 18(11), 2781–2790. *https://doi.org/10.1111/ajt.14985;* Patzer, R.E., McPherson, L., Basu, M., Mohan, S., Wolf, M., Chiles, M., Russell, A., Gander, J.C., Friedewald, J.J., Ladner, D., Larsen, C.P., Pearson, T., & Pastan, S. (2018). Effect of the iChoose Kidney decision aid in improving knowledge about treatment options among transplant candidates: A randomized controlled trial. American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 18(8), 1954–1965. *https://doi.org/10.1111/ajt.14693.*

[272] Stephenson, M. Stephenson, M. Stephenson, M. Stephenson, M.D., & Bradshaw, W. (2018). Shared decision making in chronic kidney disease. *Renal Society of Australasia Journal, 14*(1), 26. *https://www.proquest.com/scholarly-journals/shared-decision-making-chronic-kidney-disease/docview/2283078287/se-2;* Gordon, E. J., Butt, Z., Jensen, S.E., Lok-Ming Lehr, A., Franklin, J., Becker, Y., Sherman, L., Chon, W.J., Beauvais, N., Hanneman, J., Penrod, D., Ison, M.G., & Abecassis, M.M. (2013). Opportunities for Shared Decision Making in Kidney Transplantation. American Journal of Transplantation, 13(5), 1149–1158. *https://doi.org/10.1111/ajt.12195;* Schold, J.D., Huml, A.M., Poggio, E.D., Reese, P.P., & Mohan, S. (2022). A tool for decision-making in kidney transplant candidates with poor prognosis to receive deceased donor transplantation in the United States. Kidney International. *https://doi.org/10.1016/j.kint.2022.05.025;* Schaffhausen, C.R., Bruin, M.J., McKinney, W.T., Snyder, J.J., Matas, A.J., Kasiske, B.L., & Israni, A.K. (2019). How patients choose kidney transplant centers: A qualitative study of patient experiences. 33(5), e13523–e13523. *https://doi.org/10.1111/ctr.13523;* Hart, A., Bruin, M., Chu, S., Matas, A., Partin, M.R., & Israni, A.K. (2019). Decision support needs of kidney transplant candidates regarding the deceased donor waiting list: A qualitative study and conceptual framework. Clinical Transplantation, 33(5), e13530. *https://doi.org/10.1111/ctr.13530;* Patzer, R.E., McPherson, L., Basu, M., Mohan, S., Wolf, M., Chiles, M., Russell, A., Gander, J.C., Friedewald, J.J., Ladner, D., Larsen, C.P., Pearson, T., & Pastan, S. (2018). Effect of the iChoose Kidney decision aid in improving knowledge about treatment options among transplant candidates: A randomized controlled trial. American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 18(8), 1954–1965. *https://doi.org/10.1111/ajt.14693.*

[273] Kucirka, L.M., Grams, M.E., Balhara, K.S., Jaar, B.G., & Segev, D.L. (2011). Disparities in Provision of Transplant Information Affect Access to Kidney Transplantation. American Journal of Transplantation, 12(2), 351–357. *https://doi.org/10.1111/j.1600-6143.2011.03865.x;* Patzer, R.E., Retzloff, S., Buford, J., Gander, J., Browne, T., Jones, H., Ellis, M., Canavan, K., Berlin, A., Mulloy, L., Gibney, E., Sauls, L., Muench, D., Reeves-Daniel, A., Zayas, C., DuBay, D., Mutell, R., & Pastan, S.O. (2021). Community Engagement to Improve Equity in Kidney Transplantation from the Ground Up: the Southeastern Kidney Transplant Coalition. Current Transplantation Reports, 8(4), 324–332. *https://doi.org/10.1007/s40472-021-00346-x;* Schold, J.D., Huml, A.M., Poggio, E.D., Reese, P.P., & Mohan, S. (2022). A tool for decision-making in kidney transplant candidates with poor prognosis to

By pairing the CollaboRATE Shared Decision-Making Score measure with the proposed achievement domain number of kidney transplants metric, as described in section III.C.5.c. of the proposed rule, and the proposed quality domain post-transplant outcomes metrics, as described in section III.C.5.e.(1). of the proposed rule, we aimed to incentivize care delivery transformation and improvement activity across IOTA participants that would center attributed patients and their family and caregiver as a critical decision-maker in treatment choices that align with their preferences and values. This may include greater transparency on donor organ offers and reasons for non-acceptance, and increased education and support on the living donor process. We also believed that this would support attributed patients in receiving a kidney that may be at higher risk of non-use, but that may offer a survival and quality of life advantage over remaining on dialysis, dying while waitlisted, or being de-listed.[274]

In section III.C.5.e(2)(b) of the proposed rule, we acknowledged that the instrument used for the CollaboRATE Shared Decision-Making Score is generic; however, we were unable to identify alternative measures of shared decision-making that are specific to kidney transplant that have been endorsed by the CBE. Similarly, while there may be value in an instrument that measures shared decision-making regarding the types of kidney organ offers attributed patients are willing to accept, no such measure exists. We believed the CollaboRATE Shared Decision-Making Score would capture variation in the presence and quality of shared decision-making among IOTA participants and that the instrument need not be specific to kidney transplant to incentivize meaningful improvements in patient-centricity and the patient experience, equity, and reducing kidney non-use.

We sought comment on our proposal to include the CollaboRATE Shared Decision-Making Score as a quality measure for purposes of quality domain performance assessment.

The following is a summary of the comments received on our proposal to include the CollaboRATE Shared Decision-Making Score as a quality measure for purposes of quality domain performance assessment and our responses:

Comment: Commenters expressed concern over the proposed inclusion of CollaboRATE Shared Decision-Making Score as a quality measure within the quality measure set to assess IOTA participant performance in the quality domain. Many commenters noted its lack of validation for use with hospitals and data to support the use of this measure in this population. Many commenters expressed concerns that the CollaboRATE measure is for use in the outpatient setting and has not been designed for hospitals or transplant patients. Many commenters questioned the inclusion of CollaboRATE Shared Decision-Making Score because it does not require transplant-related discussions and its applicability for inclusion in the model is unclear. Some commenters were concerned that the CollaboRATE Shared Decision-Making Score might not impact the specific issues of organ offers when used to capture all kidney transplant care, but pilot work and a trail funded by the NIH are specifically studying shared decision making for kidney transplant organ offers with a focus on materials and interventions to support SDM in a specific decision or encounter. Several commenters expressed concern over whether survey responses would provide relevant data for care under the IOTA Model and suggested that responses might need to be adjusted to factor in patient demographic characteristics. A couple commenters noted that it was unclear when the survey would be completed, and questioned whether administering the survey once per year, as proposed, would result in each survey covering multiple visits, making it difficult to observe quality differences or determine how to intervene. Several commenters had concerns about the amount of burden placed on transplant hospitals to implement the CollaboRATE Shared Decision-Making Score. A couple commenters indicated that this would be especially burdensome for small transplant hospitals without access to electronic sampling methods and that a focus on high response rates may limit resources for SDM.

Response: In response to these comments, we will not be finalizing our proposal to include the CollaboRATE Shared Decision-Making Score as a quality measure for purposes of assessing performance within the quality domain, as described in section III.C.5.e(2) of this final rule. We believe incentivizing SDM is critical to centering the patient experience and treatment choices in the IOTA Model. This aligns with the model's goals of improving equity, increasing kidney transplants, and reducing non-utilization, as discussed in section III.C.5.e(2)(b) of the preamble in this final rule. While we are not finalizing this SDM measure, the IOTA Model promotes it through other policies, such as the transparency requirements as described and finalized in section III.C.8(a) of the preamble in this final rule.

Comment: A few commenters expressed support for CMS's proposal to include CollaboRATE Shared Decision-Making Score as a quality measure within the quality measure set to assess IOTA participant performance in the quality domain. A commenter indicated that the CollaboRATE Shared Decision-Making Score would capture how well providers engage with patients before and after surgery and help promote patient-centered care. A commenter also expressed belief that incorporating a SDM patient-reported measure requirement is critical for transplant patients. They also suggested that incentivizing SDM between patients and healthcare providers would foster patient-centered care and promote informed choices.

Response: We thank commenters for their support and for their comments in support of our proposal to include CollaboRATE Shared Decision-Making Score as a quality measure for purposes of assessing performance within the quality domain, as described in section III.C.5.e(2) of this final rule. However, in response to public comment, we will not be finalizing the CollaboRATE Shared Decision-Making Score as a quality measure, as described in section III.C.5.e(2) of this final rule. We still believe that incentivizing shared decision-making is critical to ensuring the model centers the patient experience and treatment choice to meet the IOTA desired goals of improving equity, increasing the number of kidney transplants, and reducing kidney non-utilization, as discussed in section III.C.5.e(2)(b) of this final rule. Although we are not finalizing this measure at this, we think that the IOTA Model promotes SDM through some of our other policies, such as the proposed

receive deceased donor transplantation in the United States. Kidney International. *https://doi.org/10.1016/j.kint.2022.05.025;* Patzer, R.E., McPherson, L., Basu, M., Mohan, S., Wolf, M., Chiles, M., Russell, A., Gander, J.C., Friedewald, J.J., Ladner, D., Larsen, C.P., Pearson, T., & Pastan, S. (2018). Effect of the iChoose Kidney decision aid in improving knowledge about treatment options among transplant candidates: A randomized controlled trial. American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 18(8), 1954–1965. *https://doi.org/10.1111/ajt.14693.*

[274] Massie, A.B., Luo, X., Chow, E.K.H., Alejo, J.L., Desai, N.M., & Segev, D.L. (2014). Survival benefit of primary deceased donor transplantation with high-KDPI kidneys. *American Journal of Transplantation, 14*(10), 2310–2316. *https://doi.org/10.1111/ajt.12830.*

transparency requirements as described and finalized in section III.C.8(a) of the preamble in this final rule.

After consideration of the public comments we received, for the reasons set forth in this rule, we are not finalizing our proposal to include the CollaboRATE Shared Decision-Making Score as a measure within the quality measure set to assess IOTA participant performance in the quality domain.

(c) Colorectal Cancer Screening

In section III.C.5.e(2)(C) of the proposed rule, we stated that the Colorectal Cancer Screening (COL) measure identifies the percentage of patients 50–75 years of age who had guideline concordant screening for colorectal cancer. Kidney transplant recipients are at higher risk for cancer than the general population, due in part to long-term immunosuppression.[275] Kidney transplant recipients have a higher incidence of colorectal cancer and advanced adenomas and may have worse prognoses than the general population, both of which support improved screening and prophylactic care for kidney transplant recipients.[276] [277] [278]

The COL measure is a Universal Foundation measure in the CMS Meaningful Measures 2.0 Wellness and Prevention Domain. By nature of its inclusion in the Universal Foundation measure set, the COL measure addresses a condition associated with significant morbidity and mortality and incentivizes action on high-value preventive care.[279] The COL measure is also aligned with the goals of the President's Cancer Moonshot to reduce the death rate from cancer by 50 percent over the next 25 years and improve the experience of people living with cancer and those who have survived it.[280]

As described in section III.C.5.e(2)(c) of the proposed rule, we proposed the COL measure for inclusion in our assessment of quality domain performance in the model because we believed it would provide a signal of the importance of ongoing post-transplant care and reduce variation in the screening and prophylactic care of kidney transplant recipients by transplant hospital. We proposed that IOTA participants would be required to administer the COL measure yearly to all attributed IOTA transplant patients who are Medicare beneficiaries. The COL measure would work in concert with the proposed composite graft survival metric to increase the likelihood that attributed patients in the IOTA Model would receive comprehensive post-transplant care that would account not only for the attributed patient and graft survival, but also complications and comorbidities associated with receiving a kidney transplant.

We sought comment on our proposal to include the COL measure as a quality measure for purposes of quality domain performance assessment.

The following is a summary of the comments received on our proposal to include the COL measure as a quality measure for purposes of quality domain performance assessment and our responses:

Comment: Many commenters expressed concerns about our proposal to include the COL measure as a quality measure for purposes of quality domain performance assessment. Specifically, some commenters noted that many transplant recipients return to community providers after their transplant, making it challenging for transplant hospitals to ensure appropriate post-transplant screenings after they are no longer responsible for overseeing their care. As described in section III.C.5.e.(2).(c). of this final rule, we proposed that IOTA participants would be required to administer the COL measure yearly to all attributed IOTA transplant patients who are Medicare beneficiaries. A couple commenters suggested that the COL measure, as proposed, would more accurately reflect the care provided by patients' primary care physicians, since many transplant hospitals transfer the patients' care back to their local primary care physicians. A few commenters noted that transplant hospitals are already required to administer the COL to patients prior to waitlisting; suggesting that its inclusion in the IOTA Model would be redundant and unnecessarily increase costs without improving patient care. Many commenters urged CMS to remove COL from inclusion in the IOTA Model; citing that this measure is unrelated to transplant outcomes, cancers other than colorectal cancer are much more common in transplant recipients, the measure was not designed to identify the quality of care, is not a transplant-specific quality measure and shifts primary care responsibilities to transplant hospitals as reasons for its removal. Some commenters felt that the inclusion of COL in the IOTA Model is redundant and not directly relevant to kidney transplant care and suggested removing COL or replacing it with quality measures more closely aligned to kidney transplant outcomes, such as a more comprehensive cancer screening protocol.

Response: We thank commenters for sharing their concerns. In response to these comments, we will not be finalizing our proposal to include the COL measure as a quality measure for purposes of assessing performance within the quality domain as described in section III.C.5.e.(2). of this final rule.

After consideration of the public comments we received, for the reasons set forth in this rule, we are not finalizing our proposal to include the COL as a measure within the quality measure set to assess IOTA participant performance in the quality domain, as discussed in section III.C.5.e.(2). of this final rule.

(d) 3-Item Care Transition Measure (CTM–3)

As described in section III.C.5.e.(2).(d). of the proposed rule, the 3-Item Care Transition Measure (CTM–3) is a hospital-level, patient-reported measure of readiness for self-care at time of discharge from an acute care hospital. The CTM–3 is based on data from a three-question instrument that assesses whether the patient and family's preferences were accounted for in the care plan; whether patients understood their role in self-management; and, whether appropriate medication education was provided. A higher score on the CTM–3 reflects a higher quality transition of care. We proposed that IOTA participants would be required to administer the CTM–3 to attributed patients once per PY, at minimum, and report quality measure data to CMS during survey and reporting windows, as defined and finalized in section III.C.5.e(2)(a) of this

[275] Rama, I., & Grinyó, J.M. (2010). Malignancy after renal transplantation: The role of immunosuppression. Nature Reviews Nephrology, 6(9), 511–519. *https://doi.org/10.1038/nrneph.2010.102.*

[276] Komaki, Y., Komaki, F., Micic, D., Ido, A., & Sakuraba, A. (2018). Risk of colorectal cancer in chronic kidney disease. Journal of Clinical Gastroenterology, 52(9), 796–804. *https://doi.org/10.1097/mcg.0000000000000880.*

[277] Privitera, F., Gioco, R., Civit, A.I., Corona, D., Cremona, S., Puzzo, L., Costa, S., Trama, G., Mauceri, F., Cardella, A., Sangiorgio, G., Nania, R., Veroux, P., & Veroux, M. (2021). Colorectal cancer after Kidney Transplantation: A screening colonoscopy case-control study. Biomedicines, 9(8), 937. *https://doi.org/10.3390/biomedicines9080937.*

[278] Farrugia, D., Mahboob, S., Cheshire, J., Begaj, I., Khosla, S., Ray, D., & Sharif, A. (2014). Malignancy-related mortality following kidney transplantation is common. Kidney International, 85(6), 1395–1403. *https://doi.org/10.1038/ki.2013.458.*

[279] Jacobs, D.B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the Universal Foundation. New England Journal of Medicine, 388(9), 776–779. *https://doi.org/10.1056/nejmp2215539.*

[280] Cancer Moonshot. (n.d.). The White House. *https://www.whitehouse.gov/cancermoonshot/.*

final rule, that would be established by CMS.

Transitions of care after kidney transplant are common and indicate elements of modifiable transplant hospital quality. One study found that 30-day hospital readmissions after an organ transplant were significantly associated with graft loss and death.[281] Poor understanding of and adherence to immunosuppressive drugs were identified as key elements associated with an increased risk for early hospital readmission.[282] Mitigating readmission risk may be of special importance given that IOTA participants may choose to increase their number of transplants by transplanting more kidneys that may have clinical value to patients. Simultaneously, there may also be increased healthcare utilization needs due to delayed graft function (DGF), which could require longer hospital stays, readmissions, and more complex care coordination.[283] We have also heard from interested parties about the need for patient-reported measures to contribute to the assessment of post-transplant outcomes.

The CTM–3 is a patient-reported measure and would measure transplant hospital performance on an aspect of care that we understand to be important to the patient experience, modifiable by transplant hospitals, and that may not otherwise improve based on the financial incentives in the model targeted towards one- and three-year outcomes, but not directly at perioperative transitions of care and readmission risk. The CTM–3 is a domain of the HCAHPS (CBE ID: 0166). We believe that IOTA participants would have some familiarity with the HCAHPS survey and that the hospital systems of which IOTA participants would be a part would have an infrastructure in place for the administration of HCAHPS that could be leveraged to support administration of the CTM–3.

We sought comment on our proposal to include the CTM–3 measure as a quality measure as a quality measure for purposes of quality domain performance assessment.

The following is a summary of the comments received on our proposal to include the CTM–3 measure as a quality measure for purposes of quality domain performance assessment and our responses:

Comment: Many commenters urged CMS not to finalize CTM–3 as a quality measure within the quality measure set to assess IOTA participant performance in the quality domain, noting that it would add additional burden to patients and IOTA participants and unnecessary complexity, and cost to IOTA participants. A couple commenters urged CMS not to include the CTM–3 measure, indicating that the association between CTM–3 and readmissions is inconsistent in that it does not predict 30-day outcomes and only weakly predicts 3- and 12-month outcomes. Several commenters also noted that participants would be required to report the CTM–3 separately from their HCAHPS surveys, as this measure will soon be removed from the revised Inpatient Quality Reporting Program (IQR). A commenter also noted that collecting CTM–3 data could be redundant, as it will soon be removed from the hospital IQR in favor of an updated set of HCAHPS care coordination items. Finally, a commenter stated that they opposed the inclusion of CTM–3 as a quality measure within the quality measure set to assess IOTA participant performance in the quality domain.

Response: We thank the commenters for their comment and appreciate these commenters concerns to our proposal to include the CTM–3 measure as a quality measure for purposes of assessing performance in the quality domain. In response to these comments, we will not be finalizing our proposal to include the CTM–3 measure as a quality measure for purposes of assessing performance within the quality domain, as described in section III.C.5.e(2) of this final rule.

Comment: Some commenters recommended alternative measures that CMS should consider replacing the CTM–3 with. For example, several commenters suggested that CMS should replace the retired CTM–3 measure with the proposed ''Care Coordination'' Sub-Measure to align with the updates to the HCAHPS survey. A commenter suggested that CMS should consider only looking at readmission rates as a proxy for sound care transition planning or using HCAPS data instead of the CTM–3 measure.

Response: We thank the commenters for their comment and appreciate these commenters suggested alternatives to our proposal to include the CTM–3 measure as a quality measure for purposes of assessing performance in the quality domain. In response to the public comments we received, we will not be finalizing our proposal to include the CTM–3 measure as a quality measure for purposes of assessing performance within the quality domain as described in section III.C.5.e(2) of this final rule.

Comment: A couple commenters expressed support for the inclusion of CTM–3 as a quality measure within the quality measure set to assess IOTA participant performance in the quality domain. A commenter urged CMS to finalize this measure suggesting that it would encourage providers to actively engage patients before and after surgery to ensure they can make an informed decision about their treatment options and are prepared to manage their care afterwards.

Response: We thank commenters for their support and for their comments in support of our proposal to include the CTM–3 measure as a quality measure for purposes of quality domain performance assessment. We believe that transitions of care after kidney transplant are common and indicate elements of modifiable transplant hospital quality, as discussed in section III.C.5.e(2)(d) of this final rule. However, as described in comment responses noted previously, due to concerns raised by commenters we will not be finalizing CTM–3 as a quality measure, as described in section III.C.5.e(2) of this final rule. We will continue to evaluate the changing inventory of quality measures, considering public input, and intend to propose alternative quality measures through future notice and comment rulemaking

After considering public comments, for the reasons set forth in this rule, we are not finalizing our proposal to include the CTM–3 as a measure within the quality measure set to assess IOTA participant performance in the quality domain, as described and finalized in section III.C.5.e(2) of this final rule.

(e) Calculation of Points

In section III.C.5.e(2)(e) of the proposed rule, we proposed that the IOTA participant would receive up to 10 points for performance on our three proposed measures within the quality domain—the CollaboRATE Shared Decision-Making Score, COL, and CTM–3 measures. For purposes of quality measure set performance scoring, we proposed that IOTA participants may

[281] Covert, K.L., Fleming, J.N., Staino, C., Casale, J.P., Boyle, K.M., Pilch, N.A., Meadows, H.B., Mardis, C.R., McGillicuddy, J.W., Nadig, S., Bratton, C.F., Chavin, K.D., Baliga, P.K., & Taber, D.J. (2016). Predicting and preventing readmissions in Kidney Transplant Recipients. *Clinical Transplantation, 30*(7), 779–786. *https://doi.org/10.1111/ctr.12748.*

[282] Covert, K.L., Fleming, J.N., Staino, C., Casale, J.P., Boyle, K.M., Pilch, N.A., Meadows, H.B., Mardis, C.R., McGillicuddy, J.W., Nadig, S., Bratton, C.F., Chavin, K.D., Baliga, P.K., & Taber, D.J. (2016). Predicting and preventing readmissions in Kidney Transplant Recipients. *Clinical Transplantation, 30*(7), 779–786. *https://doi.org/10.1111/ctr.12748.*

[283] Jadlowiec, C.C., Frasco, P., Macdonough, E., Wagler, J., Das, D., Budhiraja, P., Mathur, A.K., Katariya, N., Reddy, K., Khamash, H., & Heilman, R. (2022). Association of DGF and early readmissions on outcomes following Kidney Transplantation. *Transplant International, 35. https://doi.org/10.3389/ti.2022.10849.*

receive up to 4 points for performance on the CollaboRATE Shared Decision-Making Score measure, up to 2 points on the COL measure, and up to 4 points on the CTM–3 measure. Lower weight in terms of scoring points were given to the COL measure because it is a claims-based measure that does not require reporting from IOTA participants. Because the CTM–3 and CollaboRATE are PRO–PMs we believed it was important to allot more points to them, to recognize the additional operational activities necessary for IOTA participants.

In section III.C.5.e(2)(e) of the proposed rule, we proposed to phase-in quality performance benchmarks for the three quality measures selected for the IOTA quality measure set, such that we would reward reporting for the first two years of the model performance period (''pay-for-reporting''), at minimum, before we reward performance against quality performance benchmarks for each measure (''pay-for-performance''). Thus, performance for each of these three quality measures would be measured against a ''response rate threshold'' applicable to our proposed ''pay-for-reporting'' method for PY 1—PY 2, while performance would be measured against quality performance benchmarks calculated by CMS applicable to our proposed ''pay-for-performance'' method for PY 3—PY 6. Table 10 illustrates our proposed pay-for-reporting and pay-for-performance timeline. We noted that we anticipated establishing a quality performance benchmarks and minimum attainment levels for quality measures in future rule making.

TABLE 10: MEASURE PAYMENT TYPE BY PERFORMANCE YEAR

Measure	PY 1	PY 2	PY 3	PY 4	PY 5	PY 6
CollaboRATE Shared Decision-Making Score	Pay for Reporting (P4R)	P4R	Pay for Performance (P4P)	P4P	P4P	P4P
Colorectal Cancer Screening (COL)	P4R	P4R	P4P	P4P	P4P	P4P
CTM-3	P4R	P4R	P4P	P4P	P4P	P4P

In section III.C.5.e(2)(e) of the proposed rule, we proposed that CMS would determine and share with IOTA participants the response rate threshold by the first day of each PY in a form and manner chosen by CMS. We stated that this approach to assessing IOTA participant quality performance would serve four key purposes. First, it would promote measure implementation, uptake, and data collection by IOTA participants through a rewards-only scoring system. Second, it would build experience over the first two model PYs, giving IOTA participants more time to prepare and build capacity to meet performance benchmarks. Third, it would allow CMS to collect data needed to develop measure benchmarks. Finally, it would focus model incentives on care delivery transformation and improvement activity directly aimed at meeting quality performance goals, as to ensure the patient is centered in this approach. Ultimately, we considered the pay-for-reporting approach to be a reasonable approach. We also believed that some IOTA participants may be familiar with this as it is similar to the format within the KCC Model. We recognized that these measures already exist, but, because they are used in a much broader population, there are no benchmarks that are applicable for the model.

In section III.C.5.e(2)(e) of the proposed rule, we proposed to define the ''response rate threshold'' as the level of complete and accurate reporting for each quality measure, within the quality measure set of the quality domain, that the IOTA participant must meet to earn points on the quality domain during a performance year as described in § 512.428(c) and (e) of the proposed rule. For the CTM–3 and CollaboRATE measures, we proposed that points be awarded based on response rate thresholds, as illustrated in Table 11, such that IOTA participants with a response rate threshold of—

- 90–100 percent of attributed patients would receive 4 points;
- 50–89 percent of attributed patients would receive 2 points; or
- Under 50 percent of attributed patients would receive 0 points.

In section III.C.5.e(2)(e) of the proposed rule, we proposed for the COL measure that a completion rate of 50 percent or greater would result in the IOTA participant receiving two points, and a completion rate of less than 50 percent would result in the IOTA participant receiving zero points, as illustrated in Table 11.

TABLE 11 — IOTA MODEL QUALITY MEASURE SET SCORING

Measure	Performance Relative to Target	Lower Bound Condition	Upper Bound Condition	Points Earned
CollaboRATE/CTM-3	90% Response Rate	Equals 90%	Greater than 90%	4
CollaboRATE / CTM-3	50% Response Rate	Equals 50%	Less than 90%	2
CollaboRATE / CTM-3	50% Response Rate	N/A	Less than 50%	0
COL	50% Response Rate	Equals 50%	Greater than 50%	2
COL	50% Response Rate	N/A	Less than 50%	0

As described in section III.C.5.e(2)(e) of the proposed rule, we recognized that the proposed response rate thresholds are high, but we want to make sure that we have enough data to set appropriate and meaningful benchmarks in PY 3 through PY 6. We considered setting a higher maximum measure completion rate; however, given that each IOTA participant may have different levels of engagement with kidney transplant waitlist patients, we felt a higher threshold may be difficult for IOTA participants to achieve. We also believed that a higher response rate

would incentivize IOTA participants to collect the data. We considered the following variations to the response rate threshold for each of the proposed quality measure:

- Response rate threshold of 100 percent would receive 10 points, if not 100 percent 0 points would be awarded.
- Response rate threshold of 80–100 percent would receive 10 points, 50–79 percent would receive 5 points, and 49–0 percent would receive 0 points.
- 50–100 percent would receive 10 points; under 50 percent would receive 0 points.

As described in section III.C.5.e(2)(e) of the proposed rule, we considered mirroring the point structure under which an IOTA participant would receive either all possible points, or, if data was not collected from all their attributed patients, none of the possible points. We thought that this could incentivize IOTA participants to administer the surveys associated with the proposed quality measures, which would allow us to create meaningful benchmarks for future model years. However, because there would be some additional burden placed onto IOTA participants to administer the surveys associated with the proposed quality measures, we believed this point structure would be difficult for some and wanted to provide more attainable response rate thresholds. We also considered lowering the response rate thresholds for the same reasons mentioned earlier, but, because there are currently no benchmarks for these measures in this specific population, we felt that the response rate threshold needed to be higher but still attainable.

We also considered achievement and improvement scoring for the proposed quality measures. However, because none of the measures included in the proposed quality measure set, as described in section III.C.5.e(2) of this final rule, currently have benchmarks, we did not believe it was appropriate to propose achievement and improvement scoring for the proposed quality measures at this time.

We sought comment on our proposed calculation of points for the quality measure set, as well as the proposal to reward IOTA participant reporting for the first two PYs (''pay-for-reporting''), before rewarding IOTA participant performance against quality performance benchmarks. We sought comment on the proposed response rate thresholds and point allocations for measures included in the proposed quality measure set within the quality domain.

The following is a summary of the comments received on our proposed calculation of points for the quality measure set, as well as the proposal to reward IOTA participant reporting for the first two PYs (''pay-for-reporting''), before rewarding IOTA participant performance against quality performance benchmarks and the proposed response rate thresholds, point allocations for measures included in the proposed quality measure set within the quality domain and our responses:

Comment: Some commenters expressed concern about the proposed response rate thresholds and point allocations and requested that CMS lower the proposed response rate threshold for the proposed quality measures. For example, a commenter expressed their belief that how well IOTA participants do getting their patients to respond to specific surveys is not an accurate reflection of quality. A few of commenters indicated that transplant hospitals currently struggle to achieve patient experience survey response rates above 30 percent. Given this challenge, they felt that the proposed 90 percent response rate threshold for quality measures is unrealistic. To achieve a 90 percent response rate for two new quality measures, a commenter suggested this would require that the surveys be administered in person; noting that this approach could create an administrative burden by requiring staff to distribute and collect the surveys, as well as necessitate patients making extra clinic visits solely for the purpose of completing the surveys. Several commenters urged CMS to adjust the response rate thresholds to mitigate this challenge. Specifically, a commenter recommended that CMS adopt a similar minimum response rate threshold like what is proposed for awarding domain points; suggesting 4 points awarded for response rate thresholds above 50 percent, 2 points awarded for response rate thresholds of 25 percent to 50 percent, and 0 points awarded for response rates below 25 percent.

Response: We thank these commenters for sharing their concerns. We acknowledge the concerns related to the high response rate thresholds proposed for the CollaboRATE Shared Decision-Making Score and CTM–3. As we stated in the proposed rule, we acknowledge that the proposed response rate thresholds are quite high and that these measures are already in use, though applied to a much wider population. As a result, there are no benchmarks that can be utilized for the IOTA Model, and we sought to ensure that we had enough data to set appropriate and meaningful quality performance benchmarks in PY 3 through PY 6.

We also thank the commenters for their recommendations to lower the response rate thresholds given the number of surveys requests and obligations transplant patients are already asked to complete and the additional burden that could be placed onto IOTA participants to administer the surveys associated with the proposed quality measures and lower the response rate thresholds. We also appreciate the commenters suggestion for an alternative scoring methodology. As we stated in the proposed rule, we did consider lowering the response rate thresholds for the same reasons mentioned earlier, but, because there are currently no benchmarks for these measures in this specific population, we felt that the response rate threshold needed to be higher but still attainable. We direct readers to section III.C.5.e.(2)(e) for further discussion on the alternative scoring methodologies that were considered for inclusion in the IOTA Model. We also note that we considered the added reporting burden on IOTA participants when evaluating potential quality measures for inclusion in the IOTA Model, and direct commenters to section III.C.5.e(2) of this final rule for further discussion.

Lastly, because we are not finalizing our proposed quality measure set, as described in section III.C.5.e(2) of this final rule, and in consideration on public comment received, we will not be finalizing our proposed quality measure set scoring methodology. In section III.C.5.e(e) of the proposed rule, we proposed that the IOTA participant would receive up to 10 points for performance on our three proposed measures within the quality domain while also noting in the proposed rule at 89 FR 43564, that if we finalize fewer measures, then we proposed to allocate the points accordingly within the remaining measures. Given that we are not finalizing any of the proposed measures within the quality measure set or quality measure set scoring methodology, the 10 points we proposed to award IOTA participants for performance on our three proposed measures within the quality domain will be allocated to the composite graft survival rate within the quality domain, as described and finalized in section III.C.5.e(1)(b) of this final rule.

Although we are not finalizing our quality measure set scoring methodology at this time, CMS will take into consideration the commenters concerns and suggestions and intends to propose an alternative or updated policy

proposal in future notice and comment rulemaking.

Comment: A couple commenters expressed support for the proposed response rate thresholds, but they felt that a 90% response rate would be extremely unlikely to be achieved.

Response: We thank commenters for their support and for their comments in support of our proposed response rate thresholds and concern over the achievability of a 90% response rate. As mentioned in comment responses noted previously, we acknowledge that the response rate thresholds we proposed were high. As discussed in the preamble of this final rule, we proposed the response rates for the proposed quality measures, as illustrated in Table 11 noted previously, to allow CMS to collect enough data to develop meaningful and appropriate measure benchmarks in PYs 3–6.

However, because we are not finalizing our proposed quality measure set, as described in section III.C.5.e(2) of this final rule, and based on public comment, we will not be finalizing our proposed quality measure set scoring methodology, as described in section III.C.5.e(2)(e) of this final rule, at this time, and intend to propose a new or updated policy in future notice and comment rulemaking that will address concerns with respect to response rate thresholds IOTA participants may have.

Comment: A couple commenters requested that CMS provide additional clarity about the proposed response rate thresholds and point allocations. For example, a commenter urged CMS to not only propose response rate thresholds, but also define what constitutes ''complete and accurate reporting'' and provide specifics on how the response rate threshold would be calculated for CollaboRATE; stating that until CMS did so, they could not support the inclusion of this measure in the IOTA Model. Another commenter cited that the Healthcare Effectiveness Data and Information Set (HEDIS) specifications for the COL measure indicate that COL is an administrative measure,[284] noting that CMS proposed response rate thresholds for it during the pay-for-reporting years of the model. This commenter asked CMS to clarify two key points: (1) How the response rate would be calculated for an administrative measure, and (2) How this calculation differs from the quality performance benchmarks that would need to be met once the measure transitions to pay-for-performance in future program years.

Response: We appreciate the commenters comments and clarifying questions. In the proposed rule at 89 FR 43658, we proposed to define response rate threshold as the level of complete and accurate reporting for each quality measure, within the quality measure set of the quality domain, that the IOTA participant must meet to earn points on the quality domain during a performance year as described in §§ 512.428(c) and 512.428(e). In response to the commenters request that CMS further explain how the response rate threshold would be calculated for CollaboRATE and COL, we clarify here that, based on our proposed definition and industry standards, the response rate for each of the proposed quality measures would be calculated as follows:

Equation 5: Response Rate Threshold

$$Response\ Rate\ = \frac{\#\ of\ complete\ and\ accurate\ responses\ submitted}{\#\ of\ eligible\ attributed\ patients\ surveyed} X100$$

For example, if in PY 1 of the model, an IOTA participant was required to administer the CollaboRATE to 30 of their attributed patients and submitted 28 complete and accurate responses, the response rate for that IOTA participant on the CollaboRATE would be 93% (28 complete and accurate responses submitted divided by 30 and then multiplied by 100). Based on our proposed quality measure set scoring methodology, as described in the preamble of this final rule, that IOTA participant would be awarded four points for their response rate threshold on the CollaboRATE.

In accordance with the Share Savings Program Final Rule as outlined in 76 FR 67873, we are clarifying that ''complete and accurate reporting'' signifies that that the quality data submitted to CMS is accurate, complete, and truthful. However, we disagree with the commenters' belief that CMS needs to define what is meant by ''complete and accurate reporting,'' as this is language that has been used in other models, such as the Shared Savings Program at 42 CFR 425.502. Regarding the commenters request that CMS clarify how our proposals for calculating response rate thresholds differs from calculating performance benchmarks in later PYs, we note that, as discussed in the proposed rule at 89 FR 43658, we anticipated establishing quality performance benchmarks and minimum attainment levels for quality measures in future rule making.

Finally, as mentioned in comment responses noted previously in this section, since we are not finalizing our proposed quality measure set, as described in section III.C.5.e(2) of this final rule, and based on public comment, we will not be finalizing our proposed quality measure set scoring methodology at this time and the 10 points we proposed to award IOTA participants for performance on our three proposed measures within the quality domain will be allocated to the composite graft survival rate within the quality domain, as described and finalized in section III.C.5.e(1)(b) of this final rule. We also note that we intend to propose a new or updated policy in future notice and comment rulemaking.

After consideration of the public comments we received, for the reasons set forth in this rule, we are not finalizing our proposed quality measure set scoring methodology, as described at § 512.428(e) of the proposed rule, or our proposed definition of response rate threshold, as described at § 512.402 of the proposed rule. Although we are not finalizing any of the measures that we proposed for inclusion in our proposed quality measure set, as described in section III.C.5.e(2) of this final rule, we intend to propose alternatives in future notice and comment rulemaking. Additionally, in section III.C.5.e(e) of the proposed rule, we proposed that the IOTA participant would receive up to 10 points for performance on our three proposed measures within the quality domain while also noting in the proposed rule at 89 FR 43564, that if we finalize fewer measures, then we proposed to allocate the points accordingly within the remaining measures. Given that we are not finalizing the proposed quality measure set within the quality domain or quality measure set scoring methodology, the 10

[284] National Committee for Quality Assurance. ''Colorectal Cancer Screening—NCQA.'' NCQA, 2024, *www.ncqa.org/hedis/measures/colorectal-cancer-screening/*.

points we proposed to award IOTA participants for performance on our three proposed measures within the quality domain will be allocated to the composite graft survival rate within the quality domain, as described and finalized in section III.C.5.e(1)(b) of this final rule. We will continue to assess our quality domain methodology and how to best balance incentives in the efficiency domain and quality domain and will address a new or updated policy pursuant to future notice and comment rulemaking.

■ 6. Payment

a. Purpose and Goals

We believe that risk-based payment arrangements in Innovation Center models drive healthcare innovation and transform the healthcare payment system by rewarding value over volume. Risk-based payment models hold participants financially accountable, as these payments are structured to incentivize value-based care that improves quality and reduces total cost of care for beneficiaries. Risk-based payment models may be upside-risk only, or have two-sided, upside and downside, risk. Under these risk-based arrangements, IOTA participants may receive a payment from CMS if performance goals are met or exceeded, and, if the model features downside risk, may owe a payment to CMS for failing to meet performance goals.[285]

For the IOTA Model, we proposed an alternative payment model (APM) structure that incorporates both upside and downside risk to existing Medicare fee-for-service (FFS) payments for kidney transplantations as described in section III.C.6.b. of the proposed rule.

The IOTA Model will test whether performance-based payments, including an upside risk payment and 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. As described in section III.C.5. of this final rule, IOTA participants will be assessed against proposed metrics to assess performance for each PY relative to specified targets, thresholds, or benchmarks proposed and determined by CMS. The final performance score, not to exceed a maximum of 100 points, will determine if and how upside and downside risk payments are applied, as described in section III.C.6.c. of this final rule. We believe this upside and downside risk approach will be a strong incentive to promote performance improvement.

We sought comment on our proposed two-sided risk payment design to incentivize model performance goals.

The following is a summary of the comments received on our proposed two-sided risk payment design and our responses:

Comment: We received multiple comments pointing out that kidney transplant hospitals do not make their decisions for transplants based on financial incentives and that it is inappropriate to incentivize IOTA participants to do more transplants through a pay-for-performance model.

Response: We understand that the decision to transplant a specific beneficiary is not made for financial reasons. However, we recognize that resource allocation decisions for a kidney transplant hospital are made at an administrative level that will allocate resources in part based on CMS reimbursement policies, which is why we are testing the IOTA Model using this framework.

Comment: We received a comment saying that CMS should consider the impact on private payer COE programs for transplant based on the incentives in the model.

Response: We recognize the importance of COE programs to kidney transplant hospitals and recognizes that being in a COE for a payer is a key source of revenue for many kidney transplant hospitals. The model was designed to align with many of the metrics used for a COE, which generally include a minimum volume requirement and some minimum level of performance on post-transplant outcomes. Though their metrics do not generally include a major requirement to increase volume like those of the IOTA Model, transplants represent a major source of potential savings on the plan side, just as it does for CMS. CMS is hopeful that with the finalization of the IOTA Model that other payers will more closely harmonize their measures to create a unified regulatory framework that reduces burden for kidney transplant hospitals and improves overall quality.

Comment: We received a comment saying that the model should not focus on accountability at the kidney transplant hospital level, but instead direct resources directly to the most vulnerable patients to assist them through the transplant process.

Response: We understand the comment, but ultimately disagree with the commenter. The IOTA Model is based on the idea that the kidney transplant hospital is the key locus for the transplant process, given the role of the kidney transplant hospital in getting candidates onto the waitlist, deciding which organs to accept, performing transplant surgeries, managing the living donor process, and overseeing post-transplant care. Given that role, we believe that the kidney transplant hospitals are closer to their patients and will be better able to determine their exact needs to help get them through the transplant process.

Comment: We received a comment saying that downside risk in the IOTA Model was inappropriate because organ supply is out of the control of kidney transplant hospitals.

Response: We recognize that kidney transplant hospitals are not the entities responsible for recovering organs. However, research has shown significant variance in organ-offer acceptance practices, even among kidney transplant hospitals that are geographically proximate, as discussed in the background section. Additionally, kidney transplant hospitals are in complete control of the living donor kidney process, which is not dependent upon the procurement process.

Comment: We received multiple comments saying that downside risk in the model was inappropriate because kidney transplant hospitals are new to value-based care.

Response: We understand the need for IOTA participants to ramp up their value-based care operations, which is why there is no downside risk for IOTA participants in PY 1. Additionally, in this final rule, we removed many requirements that may have been perceived as burdensome by kidney transplant hospitals, such as reporting on multiple quality measures and on declined organ offers and we believe that this will make it more achievable for IOTA participants to devote the necessary resources required to succeed in the IOTA Model. The IOTA Model also focuses on major functions and activities that kidney transplant hospitals are already doing, rather than changing the focus to a more population health perspective as is done in many other Innovation Center models. Given these circumstances, we then believe that downside risk can be fairly applied in PY 2 to help further incentivize performance in the model.

Comment: We received a comment saying that many kidney transplant hospitals face structural barriers that prevent them from increasing their numbers of transplants, making downside risk inappropriate for the model.

Response: We recognize that different kidney transplant hospitals face

[285] *https://www.cms.gov/priorities/innovation/key-concepts/risk-arrangements-health-care.*

different limitations in how they manage the transplant process. This is why the IOTA Model includes a flexible scoring system that gives IOTA participants different areas to focus on to achieve an upside risk payment under the model. Every IOTA participant can adjust their organ offer filters to be more efficient and remove offers that they are unlikely to use. Additionally, the model is not prescriptive on how IOTA participants can transplant more organs, meaning that IOTA participants could invest in their living donor program or could focus on using deceased donor organs that they may not have utilized in the baseline years. Finally, each IOTA participant is judged against scored based on their own historic number of transplants, or historic organ offer acceptance rate, for the achievement and efficiency domains. This approach demonstrates CMS's effort to recognize that kidney transplant hospitals are starting at different places before the IOTA Model and to provide an opportunity to fostering innovation by competing against their own historic performance.

Comment: We received a comment saying that many smaller or essential kidney transplant hospitals lack the resources to effectively participate in the IOTA Model and should have no downside risk.

Response: We understand that smaller kidney transplant hospitals may have fewer overall resources and we do not want any kidney transplant hospitals to stop offering kidney transplant services because of the IOTA Model. To address this issue, we proposed a low-volume threshold of 11 or more kidney transplants performed annually to exclude the kidney transplant hospitals with the lowest volumes, as described and finalized in section III.C.3.c of this final rule. Additionally, benchmarks for the achievement domain and efficiency domain in the IOTA Model are based on improvement relative to the IOTA participant's own historic number of transplants, or historic organ offer acceptance rate, meaning that for 80 of 100 possible points that an IOTA participant can earn for the model, they are evaluated against their own historic performance. Finally, the payment methodology for the IOTA Model is based on the number of transplants performed and includes asymmetrically less downside risk, minimizing the potential downside for smaller kidney transplant hospitals. We will monitor the effects of these different mechanisms within the IOTA Model to see if they are successful in helping smaller kidney transplant hospitals and will consider further efforts in future rulemaking based on the results of those monitoring efforts.

Comment: We received a comment supporting the two-sided risk structure for the IOTA Model, supporting the inclusion of downside risk in order to help change behavior of IOTA participants.

Response: We appreciate the feedback and believe that downside risk is ultimately necessary to help incentivize IOTA participants to achieve the goals of the IOTA Model.

Comment: A commenter questioned whether payment adjustments effectively drive physician behavior, and instead urged CMS to prioritize upstream investments as a means of promoting increased organ transplantation.

Response: We appreciate the feedback but disagree with the commenter. We recognize some of the limitations of payment adjustments to move physician behavior. However, we recognize that they have never been tried in this area. There is significant variation kidney transplant hospitals among their use of organ offer filters, organ offer acceptance rate, and investment in the living donation process, and the IOTA Model will test whether IOTA participants can learn from other IOTA participants that may be higher performing in these areas. We also recognize that organ transplant, as opposed to many other areas covered in other Innovation Center models, contains a cost-based reimbursement model for organ acquisition costs that provides a significant source of funding to support IOTA participants' investments in performance.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing this two-sided payment framework as originally designed. We believe that the two-sided framework best creates a clear incentive for improved performance by IOTA participants, with sufficient upside to reward IOTA participants for excellent performance. Furthermore, as described and finalized in section III.C.6.c(1) of this final rule, we are finalizing at § 512.430(b)(3)(i) that for PY 1, the IOTA participant does not owe a downside risk payment to CMS. We direct readers to sections III.C.6.C(2)(a-c) for a full discussion on our proposed upside risk payment, downside risk payment, and neutral zone provisions.

b. Alternative Payment Design Overview

There are two payment components in the current Medicare FFS program for organ transplantation. Under the Medicare Inpatient Prospective Payment System (IPPS), kidney transplant hospitals are paid a prospective payment system rate based on the MS–DRG for the organ transplant. Payment for organ acquisition costs as described at 42 CFR 413.402, which include costs associated with beneficiary and donor evaluation, is made on a reasonable cost basis. To remain active on the transplant waitlist, candidates must meet a variety of criteria, including annual screenings for cardiovascular diseases and cancers.

In the IOTA Model, CMS proposed two-sided performance-based payments for ''Medicare kidney transplants,'' defined 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, and as illustrated in Table 12. We stated that this APM design aligns with the Health Care Payment Learning & Action Network (LAN) Category 3 APM framework in which IOTA participants continue to be paid on the basis of Medicare FFS, but a retrospective annual attribution reconciliation and performance assessment after the end of each model PY is conducted to determine performance-based payments.[286] [287]

The IOTA Model's performance-based payments are linked to existing Medicare Part A and Part B services for kidney transplants, and align with other Innovation Center models' payment structure, including the ETC Model where upward and downward adjustments are made to certain Medicare payments under the ESRD Prospective Payment System and Physician Fee Schedule depending on an ETC Participant's performance at the aggregation group level under the model. The difference between ETC and the IOTA Model, for example, is how these retrospective adjustments would be paid or recouped by CMS. CMS did not propose to adjust existing Medicare IPPS payments for kidney transplants furnished to Medicare beneficiaries. Instead, CMS proposed to make performance-based payments to IOTA participants separate from claims-based payments.

[286] *https://hcp-lan.org/workproducts/apm-refresh-whitepaper-final.pdf.*

[287] *https://hcp-lan.org/workproducts/apm-refresh-whitepaper-final.pdf.*

TABLE 12: MS-DRGs PROPOSED FOR INCLUSION IN DEFINITION OF MEDICARE KIDNEY TRANSPLANTS

MS-DRG	Description
008	SIMULTANEOUS PANCREAS AND KIDNEY TRANSPLANT
019	SIMULTANEOUS PANCREAS AND KIDNEY TRANSPLANT WITH HEMODIALYSIS
650	KIDNEY TRANSPLANT WITH HEMODIALYSIS WITH MCC
651	KIDNEY TRANSPLANT WITH HEMODIALYSIS WITHOUT MCC
652	KIDNEY TRANSPLANT

We proposed to base performance-based payments on increasing the number of transplants and other metrics of efficiency and quality because we believe this approach: (1) would be a strong proxy for total cost; (2) directly aligns with the model's goal of increasing access to and the volume of kidney transplantations; (3) acknowledges kidney waitlist and transplant patients are high-cost and high-need, making performance based on total cost of care unfair for IOTA participants with lower volume and fewer capabilities and resources given the increased opportunity for outliers; and (4) may safeguard against unintended consequences introduced by defining value based on cost for an attributed patient population already at high-risk, such as inappropriate cost shifting and widening access to care disparities. We theorize that increasing the number of, and access to, kidney transplants alone would result in better quality. As indicated in our estimates presented in section IV of this final rule, it would also result in savings to Medicare.

While we proposed to assess model performance for each IOTA participant for all attributed patients regardless of payer type, as described in section III.C.6.c of this final rule, we proposed model performance-based payments that would only be based on kidney transplants furnished to attributed patients with Medicare FFS as their primary or secondary insurance.

As described in section III.C.6.b of the proposed rule, we considered also basing the model performance-based payments on kidney transplants furnished to attributed patients enrolled in Medicare Advantage (MA), as kidney transplants are a Medicare-covered service that MA plans must also cover. As these payments would be made to kidney transplant hospitals, a potential waiver of section 1851(i)(2) of the Act, which provides that only the MA plan shall be entitled to payments for services furnished to the beneficiary, may have been necessary to apply the payments to attributed patients enrolled in MA. Because further consideration was needed for the implications of such a potential waiver, we did not propose to apply model performance-based payments performed on attributed patients enrolled in MA.

We believed that the benefits of applying model performance-based payments to transplants furnished to attributed patients enrolled in MA would be recognizing the growth in MA enrollment relative to Medicare FFS enrollment, strengthening the model test through aligned payment incentives across payers, and protecting against unintended consequences of incentivizing inappropriate organ offer acceptance based on payer type. However, we did not propose to base payments on attributed patients enrolled in MA because of concerns about potentially waiving section 1851(i)(2) of the Act. This provision states that only the MA plan is entitled to payments for services provided to the beneficiary. We noted that waiving this requirement would be unprecedented and the effects are unknown. We recognized that the proposed incentives in the IOTA Model would have a larger effect if kidney transplant hospitals were receiving performance-based payments based on their entire panel of attributed beneficiaries who receive transplants, and not just based on transplants for attributed beneficiaries with Medicare FFS as their primary or secondary insurance. To that end, we proposed that the IOTA Model would encourage multi-payer alignment with the goal of aligning on goals, incentives, and quality. We noted in the proposed rule that CMS intended to engage with the payer community, including MA, Medicaid, and commercial payers, in future years to discuss opportunities and approaches for alignment.

We requested comment and feedback, especially from MA plans, on our decision not to calculate model performance-based payments to transplants furnished to attributed patients enrolled in MA. We were especially interested in comments that address how the Innovation Center should generally approach the growing MA population with the design of its models, which have traditionally been focused on the fee-for-service Medicare population.

While kidney transplant hospitals are subject to value-based payment programs, some IOTA participants may have limited APM experience, resources, and capacity to meet model goals. We considered an upside-risk payment only framework that would still base model payments on kidney transplant utilization and other metrics of efficiency and quality. However, we believed that two-sided risk payments would be stronger incentives to achieve the desired goals. We also recognized this in the model design by proposing a phased-in approach to two-sided risk, with only upside-risk applied to the first model PY. We also considered other APM frameworks that would link performance to quality, such as pay-for-reporting on the measures. We did not propose these frameworks, as they did not align with our goals of establishing two-sided risk accountability for IOTA participants. We recognized the benefits of a rewards-focused approach, particularly as it relates to quality performance, and we therefore did incorporate a rewards-focused performance scoring structure designed as pay-for-reporting and pay-for-performance within the quality domain performance assessment. (89 FR 43571).

Another alternative we considered was a flat positive adjustment to the Medicare FFS payment for a kidney transplant based on the number of completed kidney transplants that an IOTA participant performs. Increasing the amount paid for completed kidney transplants through a FFS adjustment is the simplest policy and aligns with the IOTA Model's focus on increasing the number of kidney transplants. Additionally, adjusting the FFS payment would directly incentivize an increase in the number of kidney transplants performed by IOTA participants. Under this approach, eligible claims would be identified utilizing Medicare claims data with Medicare Severity Diagnosis Related Groups (MS–DRGs) 008 (simultaneous pancreas-kidney transplant) and 652

(kidney transplant); and claims with ICD–10 procedure codes 0TY00Z0 (transplantation of right kidney, allogeneic, open approach), 0TY00Z1 (transplantation of right kidney, syngeneic, open approach), 0TY00Z2 (transplantation of right kidney, zooplastic, open approach) 0TY10Z0 (transplantation of left kidney, allogeneic, open approach), 0TY10Z1 (transplantation of left kidney, syngeneic, open approach), and 0TY10Z2 (transplantation of left kidney, zooplastic, open approach).

We did not propose a performance methodology based solely on adjusting the DRG payment for a kidney transplant, because this option would not encourage IOTA participants to focus on issues other than transplant volume, including equity, increased utilization of donor kidneys, quality of care, and patient outcomes, all of which are important parts of the transplant process where we believe performance is variable and can be improved. We further believe that the claims-only approach would not be as effective in incentivizing a continuous increase in transplants because IOTA participants that already have high kidney transplant volumes would be rewarded through increased reimbursements whether they improved year-over-year or not. Finally, we do not believe that this approach would provide any additional encouragement for IOTA participants to manage post-transplant care.

We also considered establishing a payment for transplant waitlist management to encourage additional investment in the transplant process, but decided to focus more on the outcomes described in section III.C.5 of the proposed rule. Additionally, given that IOTA participants are already reimbursed at cost for efforts to manage beneficiaries on the waitlist, we did not believe an explicit additional payment would be necessary in this area.

We sought feedback on our proposed alternative payment model design, data source to identify kidney transplants, and proposal to only apply model performance-based payments, both upside and downside, to Medicare FFS kidney transplants. We also sought feedback on alternative approaches considered, such as the alternative approach of including MA transplants. We welcomed input on how CMS may be able to work with multiple payers to ensure alignment with the IOTA Model.

The following is a summary of the comments we received regarding our proposed alternative payment model design, data source to identify kidney transplants, our proposal to apply model performance-based payments and our alternative approach of including MA transplants, and our responses:

Comment: We received over twenty comments urging CMS to apply the payment adjustments in the IOTA Model to transplants performed for beneficiaries with Medicare Advantage as a primary or secondary payer, and not just beneficiaries with Medicare FFS as a primary or secondary payer. Commenters pointed out the limited reach of the proposed incentives by focusing the incentives solely on a small portion of a kidney transplant hospital's overall patient panel. They were worried that the model may be ineffective without the incentive effects provided by applying the payment adjustments in the IOTA Model to more than just Medicare FFS transplants. Many commenters also pointed out that there is a rising number of beneficiaries enrolling in Medicare Advantage relative to Medicare FFS, which would decrease the effects of the model's proposed incentives over time. Commenters also pointed out that kidney transplant hospitals are paid directly through FFS Medicare for Organ Acquisition Costs for kidney transplants as defined in 42 CFR 413.402, even for beneficiaries with Medicare Advantage, due to their statutory exclusion in § 1853(k)(5) of the Act. Another commenter pointed out that in other Medicare APMs operated by the Innovation Center, when a beneficiary has transitioned from FFS Medicare to Medicare Advantage, it has made them become ineligible for payments from the APM and discouraged potential investment in those beneficiaries.

Response: We appreciate the feedback from commenters. However, we plan to finalize the policy as proposed as we do not believe that the additional incentive effects from including Medicare Advantage in the calculation for upside and downside payments are necessary at this point to provide sufficient incentive to test the model. We plan to further engage with Medicare Advantage plans to think about the incentives in the IOTA Model and those set up by Medicare Advantage plans. We also plan to monitor relative enrollment of beneficiaries who receive kidney transplants in Medicare FFS as opposed to Medicare Advantage to see if further policy changes will be necessary for future years of the IOTA Model.

Comment: Multiple commenters expressed concern that the proposed payment structure for the IOTA Model, which would make payments based only on Medicare FFS kidney transplants, could lead to IOTA participants preferring to transplant Medicare FFS patients at the expense of patients with Medicare Advantage.

Response: We appreciate the feedback from commenters as this is an outcome that we do not want. We recognize that the achievement domain is based on transplants performed across all payers and is worth the greatest number of points, which we believe will help to prevent this behavior. Additionally, we plan to monitor for potential shifts by payer as an unintended side effect of the model to ensure that this outcome does not occur, and we may consider taking additional action in future rulemaking if we see significant evidence that this is occurring.

Comment: A commenter supported our proposed policy to exclude payments for beneficiaries with Medicare Advantage from the positive and negative payment adjustments in the Model.

Response: We plan to monitor relative enrollment of beneficiaries who receive kidney transplants in Medicare FFS as opposed to Medicare Advantage to see if further policy changes will be necessary for future years of the IOTA Model.

Comment: We received a comment urging CMS to align the payments in the IOTA Model with those from Medicare Advantage plans.

Response: We recognize the importance of multi-payer alignment and has engaged in numerous conversations with Medicare Advantage plans about their transplant strategies. It is our understanding from discussions with MAOs that most MAOs use their COE programs to evaluate kidney transplant hospitals for network inclusion often provide them special contracting rates. Many plans use a variety of criteria to determine COE, including a minimum transplant volume, and minimum performance on certain outcomes metrics.[288] We believe that IOTA participants' quality improvement activities as a result of the model's performance metrics and payment methodology may help them reach and maintain COE status.

Comment: We received multiple comments urging CMS to include kidney transplants covered by other payers in the model's payment methodology, particularly the Medicaid program.

Response: Medicare is the dominant payer in the marketplace for transplants, accounting for 57 percent of adult transplants, relative to only 7 percent

[288] For instance, Aetna's criteria is here: *https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/Aetna-Institutes-of-Excellence.pdf.*

for patients with Medicaid. As such, we believe that testing the model payment incentives based on just those transplants for beneficiaries with Medicare will provide sufficient incentive to drive the increases in transplants that CMS is hoping will occur from the Model. Additionally, transplants provide additional savings for the Medicare program given that patients may become entitled to Medicare based on ESRD, and given that Medicare is the primary payer for services for the majority of patients with ESRD across the country.

However, we urge other payers, including private plans, to follow the lead of CMS and learn from the lessons we glean from this Model to evaluate how they pay kidney transplant hospitals to incentivize quality care and better outcomes.

As a result, we believe that applying these payments in the IOTA Model to all Medicare FFS transplants will apply a strong incentive for IOTA participants to increase access to kidney transplantation given Medicare's dominant role in the marketplace.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed definition of Medicare kidney transplants at § 512.402 without modification.

c. Performance-Based Payment Method

We proposed that the final performance score as described in section III.C.5. of this final rule would determine if and how an IOTA participant qualifies for an upside risk payment, falls in the neutral zone, or qualifies for a downside risk payment, proposed using a two-step process. First, we would determine if an IOTA participant's final performance score qualifies the IOTA participant for upside risk payments, downside risk payments, or the neutral zone, as described in section III.C.6.c.(1). of this final rule. Second, we would apply the proposed calculation formula for each of type of payment, as described in section III.C.6.c.(2). of this final rule. Ultimately, we proposed a performance-based payment method that prioritizes the following principles:

- Significant weight should be given to performance in the achievement domain, representing up to 60 points relative to a 100 maximum performance score, in alignment with the primary goals of the model to increase number of kidney transplants.
- The magnitude of performance-based payments should be tied to relative number of kidney transplants, given significant differentials across kidney transplant hospitals nationally.
- The largest performance-based payments amount in total dollars should go to IOTA participants that perform the most transplants because they are removing the most people from dialysis and creating the largest quality improvement and cost savings for the Medicare Trust Fund.
- The payments need to be calibrated to provide an incentive to IOTA participants, but still ensure net savings to Medicare based on the analysis performed by OACT in section IV of this final rule.
- The mechanisms should recognize that CMS has not previously offered kidney transplant hospitals a value-based care payment model around transplantation and should provide a transition to any form of downside risk to allow for an opportunity to become familiar with the value-based care process.
- Limit operational complexity for both IOTA participants and CMS to avoid any potential for errors.

(1) Determine Final Performance Score Range Category

We proposed to establish three final performance score range categories, as illustrated in Table 13, that dictate which type of performance-based payment would apply to an IOTA participant for a given PY.

We proposed at § 512.402 to define ''upside risk payment'' as a lump sum payment that CMS would make to an IOTA participant if the IOTA participant's final performance score for a PY falls within the payment range specified in section III.C.6.c(2)(a) of this final rule. As proposed and indicated in Table 13, if in PY 1–6, an IOTA participant's final performance score is greater than or equal to 60 points, the IOTA participant would qualify for an upside risk payment.

We proposed at § 512.402 to define ''neutral zone'' as the final performance score range in which the IOTA participant would not owe a downside risk payment to CMS or receive an upside-risk payment from CMS if the IOTA participant's final performance score falls within the ranges specified in section III.C.6.c.(2).(c). of this final rule. In the first year of the model, we proposed that the neutral zone would apply for final performance scores below 60. As such, only upside payments and the neutral zone would exist in PY 1. We also proposed that the neutral zone in PYs 2–6 would apply for final performance scores of 41–59 (inclusive). We believe that average performance should yield no upside or downside risk payment.

We proposed at § 512.402 to define ''downside risk payment'' as a lump sum payment the IOTA participant would be required to pay to CMS after a PY if the IOTA participant's final performance score falls within the ranges specified in section III.C.6.c.(2).(b). of this final rule. We proposed that there will be no downside risk payment in the PY 1. We proposed no downside risk payment in the first PY to allow IOTA participants time to implement changes to improve performance prior to facing downside risk. In PYs 2–6, we proposed to introduce downside risk payments. We proposed that an IOTA participant's final performance score of 40 or below in PYs 2–6, would result in a downside risk payment. We believe that below average performance should yield a downside risk payment.

The performance assessment scoring method, as described in section III.C.5. of this final rule, was designed such that IOTA participants with limited experience in APMs would still be likely to achieve a sufficient final performance score that would result in no downside risk payment. For example, it is expected that most IOTA participants would earn around 30 of 60 possible points in the achievement domain. We believe that average performance should be neither rewarded nor penalized. We also considered eliminating the neutral zone and only applying upside and downside performance payments, narrowing the neutral zone score range (that is, 44–55), or applying a wider-to-narrower phased-in approach over the model performance period. We believed these alternative options would be less flexible and more penalty-focused, with some IOTA participants more likely to be penalized due to varying degrees of capabilities and capacity that would limit their ability to achieve performance targets as they progress and evolve over the model performance period. Thus, we proposed a neutral zone that would allow for more opportunities and incentives to achieve improvements over time without a large probability of downside risk.

TABLE 13. PROPOSED 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	Neutral Zone	Neutral Zone
0 - 40	Neutral Zone	Downside Risk Payment

We sought feedback on the use of the final performance scores to determine the upside risk payment, the downside risk payment, and the neutral zone.

The following is a summary of the comments received on our proposal to use the final performance scores to determine the upside risk payment, the downside risk payment, the neutral zone and our responses:

Comment: We received multiple comments urging a delay of downside payments until PY 3 or PY 4 of the model.

Response: We believe that downside risk is an important part of testing models. We recognize the importance of transition into the model, but our thought is that the six-month starting delay, along with no downside risk in PY 1 allows for times for IOTA Participants to invest and transition into the accountability of the model, while still allowing for increased accountability in future years of the model.

Comment: A commenter noted that IOTA participants would not receive their PY 1 results until PY 2, diminishing the impact of the initial year's lack of downside risk.

Response: We understand that IOTA participants will not receive final results until into PY 2, but we know that IOTA participants are able to track their number of transplants done and their post-transplant outcomes. To help IOTA participants to better project their potential results, CMS will also share interim data reports with IOTA participants.

Comment: We received comments urging that we lower the top of the neutral zone from 60 to 50 points.

Response: In designing the scoring system, CMS wanted to make sure that performance was evaluated symmetrically, such that it would take excellent performance or performance far below what was expected to be able to get a positive or negative payment adjustment. Additionally, given the breakdown of quality points for PY 1, we believe that reaching a positive payment adjustment will be more achievable for IOTA participants to be able to earn a positive payment adjustment.

Comment: We received multiple comments recommending that we lower the points required for a downside risk adjustment, including one recommending lowering the threshold to 20 points.

Response: We considered this recommendation but decided to keep it at 40 points to balance all the different goals on the model. Given that an IOTA participant performing as expected on the achievement and efficiency domains would receive 40 points, the proposed scoring methodology is our attempt to balance the goals of being fair to IOTA participants, while also attempting to incentivize improvement on the IOTA performance metrics.

After consideration of the public comments we received, we are finalizing our proposal to use the final performance scores to determine the upside risk payment, the downside risk payment, and the neutral zone as proposed without modification at § 512.430(a). Additionally, we are finalizing as proposed the definitions of upside risk payment, and neutral zone at § 512.402 without modification. Finally, we are finalizing as proposed the definition of downside risk payment § 512.402, with a minor technical correction to include the complete cross reference to § 512.430.

(2) Apply Payment Calculation Formula to Final Performance Score

In the proposed rule at § 512.430(a), we proposed that after determining if an IOTA participant's final performance score qualifies the IOTA participant for an upside risk payment, downside risk payment, or the neutral zone, as described in section III.C.6.c(1) of this final rule, we would apply a calculation formula unique to each PY to the final performance score, as specified in sections III.C.6.c(2)(a) through (c) of this final rule.

We are finalizing this provision without modification at § 512.430(a) and direct commenters to section III.C.6.c(1) of this final rule for discussion of the methodology for determining the final performance score and the use of the final performance scores to determine the upside risk payment, the downside risk payment, and the neutral zone.

(a) Upside Risk Payment

If, in PYs 1–6, an IOTA participant's final performance score is greater than or equal to 60 points, we proposed that the IOTA participant would qualify for an upside risk payment. If an IOTA participant's final performance score would qualify them for the upside risk payment, we proposed a methodology to calculate their upside risk payment using the formula in Equation 6 below, where:

- $8,000 is a fixed, risk-based payment amount within the calculation formula, estimated to be about 33 percent of the average Medicare FFS kidney transplant MS–DRG cost. We aimed to create a strong financial incentive with significant earning opportunity for IOTA participants that meet or exceed model performance expectations. We believe this amount or proportion of the MS–DRG to be a large financial incentive to promote behavior changes while maintaining expectations of net savings to Medicare. We calibrated this based on projection of the incentive effects that would encourage the necessary support and infrastructure investment needed to achieve high performance and produce overall model savings and have the effects that we are looking for.
- The final performance score is the sum of points earned from the achievement domain, efficiency domain, and quality domain in a PY, as described in section III.C.5 of this final rule.
- Medicare kidney transplants is the number of Medicare kidney transplants furnished by the IOTA participant in a PY.

Equation 6: Proposed Upside Risk Payment Calculation Formula

$$\textit{Upside Risk Payment} = \$8{,}000 * ((\textit{Final Performance Score} - 60)/40) * \textit{Medicare Kidney Transplants}$$

We also considered calculating the maximum positive multiplier per Medicare kidney transplant claim based on the Kidney Transplant Bonus in the KCC Model. In 2019, the Kidney Transplant Bonus for entities participating in the KCC Model was set to $15,000. Adjusted for inflation, this is roughly $18,000, which would be the

maximum allowable positive bonus payment per transplant. The Kidney Transplant Bonus was originally calculated based on the difference in spending between a beneficiary who went on to get a transplant and the average ESRD beneficiary cost. However, we believed that the maximum positive adjustment may be too large in relation to current Medicare payments for kidney transplants for the model to yield net savings.

We also considered using a system similar to the Hospital VBP Program under which CMS withholds 2 percent of participating's hospitals Medicare payments and uses the sum of these reductions to fund value-based incentive payments to hospitals based on their performance under the program. However, we wished to have the opportunity for both upside and downside across IOTA participants to most effectively incentivize performance in the model.

We also considered adjusting the maximum upside multiplier in PYs 2–6; however, we felt making that decision prior to the start of the model would be premature and wish to understand IOTA participant performance before making such a decision.

We sought comment on our proposed methodology to calculate the upside risk payment and alternatives considered.

The following is a summary of the comments received on our proposed methodology to calculate the upside risk payment, alternatives considered and our responses:

Comment: We received many comments saying that the proposed payment amount was not high enough to incentivize performance in the model. Commenters pointed out a concern that they lose money on kidney transplants, based on the difference between their cost and the Medicare FFS DRG payments and that an increased number of transplants would be more likely to come from using more complex organs, which would be more expensive for the IOTA participants. Many commenters also believed that the proposed maximum upside amount of $8,000 would not be sufficient to incentivize investment by hospital leadership, particularly given that the payment amount was only proposed to be applied to Medicare FFS kidney transplants.

Response: We appreciate the feedback from commenters and recognize the validity of the concerns expressed. The IOTA Model is designed to save money for CMS, improve care for beneficiaries, to save money for Medicare, and to increase payments to IOTA participants who do more transplants. To effectively accomplish those goals, the incentives must be effectively calibrated high enough to incentivize improved performance, while still ensuring sufficient savings for CMS. We believe that applying the payment adjustments to all Medicare kidney transplants, as discussed previously will help to increase the incentives in the model and account for the changing nature of the Medicare program. Additionally, the CMS Office of the Actuary conducted additional analyses and determined that CMS would still be able to see projected savings of $22 million if the maximum upward adjustment were raised to $15,000. We considered this alternative based on the Kidney Transplant Bonus in the KCC Model, which was designed to reflect the net savings to the Medicare Trust Fund from a patient who is transplanted. Our analyses also show an average cost in 2023 of approximately $40,000 for performing MS–DRG 650, which is billed for Kidney transplants that then require hemodialysis afterwards. We recognize that many of the kidney transplants that will be performed under the IOTA Model may be for more complex organs that require hemodialysis after being transplanted and wants to recognize the increased costs to the IOTA participants for the transplant surgery and recovery when that occurs. Given that costs will grow over the course of the model period until 2030, we believe that it is appropriate to take approximately ⅓ of those costs to calculate the maximum upward adjustment, as we did for the average payment in the proposed rule, to also come up with the $15,000 figure. We proposed to keep this figure flat over the course of the model, given that it already accounts for some level of cost growth over the six-year period of the model. We will also evaluate the effects of this maximum upward adjustment and consider updating the amount based on the incentive effects and CMS savings.

Comment: We received multiple comments arguing that higher risk candidates are more expensive and are the ones who are likely to receive transplants based on the incentives in the model. Commenters urged CMS to base payment amounts on DRGs for more complex transplant surgeries given this concern.

Response: We recognize this concern from commenters and, as described in comment responses in this section, are finalizing an increased maximum upside risk payment amount of $15,000, based on the increased costs of DRG–650, which CMS projects may be necessary to be billed for the use of more complex organs.

Comment: Multiple commenters suggested that CMS should base the upward risk payment amount on the Kidney Transplant Bonus from the Kidney Care Choices Model.

Response: We recognize the validity of these comments and adjusted the amount upwards to be similar to the amount that the Innovation Center paid out in the KCC Model.

Comment: We received a comment expressing concern that the maximum upward payment amounts would not be sufficient to support IOTA collaborators, given that they would only be used by IOTA participants.

Response: We recognize the commenter's concern and believe that the increased payment amounts and increased overall payments by accounting for all Medicare kidney transplants gives the opportunity for IOTA participants to earn enough upward payments through the model to be able to support collaboration with IOTA collaborators.

Comment: We received a comment from commenters that the maximum upward adjustment should increase over the years of the model.

Response: We recognize that costs have historically risen over time and CMS payments have gone up. As a result, the updated payment amount is based on a projected rise in costs from the 2023 costs of MS–DRG 650 of $40,151. We are taking slightly more than ⅓ of that amount and keeping it as a flat rate for all six years of the model to help account for a potential rise in costs in the future. We may also re-evaluate the effects of the maximum adjustment over time based on any potential future rise in payments and the effects on the Medicare Trust Fund.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed methodology to calculate the upside risk payment upside risk payment at § 512.430(b)(1), with slight modifications. Specifically, we are making a technical correction at § 512.430(b)(1)(i) to remove the following verbiage: from 100. In the proposed rule at 89 FR 43572, we proposed that the upside risk payment would be calculated by subtracting 60 from the IOTA participant's final performance score, as outlined in Equation 2 of section III.C.6.c(2)(a) of the proposed rule. As such, we are finalizing at § 512.430(b)(1)(i) that CMS subtracts 60 from the IOTA participant's final performance score. We are also modifying our regulation at § 512.430(b)(1)(iii) to reflect a maximum upside risk payment multiplier amount of $15,000 (see Equation 7).

Lastly, we are finalizing our proposed definition of Medicare kidney transplants at § 512.402 without modification, as described and finalized in section III.C.6(b) of this final rule.

Equation 7: Upside Risk Payment Calculation Formula

$$Upside\ Risk\ Payment = \$15{,}000 * \left(\frac{Final\ Performance\ Score - 60}{40}\right) * Medicare\ Kidney\ Transplants$$

(b) Downside Risk Payment

If an IOTA participant's final performance score is at or below 40 points in PYs 2–6, the IOTA participant would qualify for a downside risk payment. If an IOTA participant qualifies for a downside risk payment, we describe the methodology to calculate their downside risk payment risk using the formula in Equation 8:

Equation 8: Proposed Downside Risk Payment Calculation Formula

*Downside Risk Payment= $2,000 * ((40 − Final Performance Score)/40) * Medicare Kidney Transplants*

- $2,000 is a fixed, risk-based payment amount within the calculation formula, estimated to be about one-twelfth, or 8 percent, of the average Medicare FFS kidney transplant MS–DRG cost. We proposed a lower downside-risk value relative to the upside-risk value proposed for the upside risk payments (about one-fourth lower) because we wanted to maintain a greater rewards approach, while still holding IOTA participants accountable for poor performance. We also believe that this approach is more flexible and accommodating to IOTA participants with no, or limited, APM experience, or that are more limited in terms of resources and capabilities.
- The final performance score is the sum of points earned from the achievement domain, efficiency domain, and quality domain, as described in section III.C.5. of this final rule.
- Medicare kidney transplants is the count of furnished Medicare kidney transplants during the PY.

We also considered applying the same fixed amount to both the upside and downside risk payment ($8,000 or $2,000 in both) or having the downside risk payment be 50 percent of the fixed amount of the upside risk payment ($4,000) but opted against it to maintain lower levels of risk given the fact that this model would be mandatory for eligible kidney hospitals. As discussed in section III.C.6.b of this final rule, we considered an upside-risk only payment framework, thus eliminating the application of downside-risk payments. Recognizing the potential for volatility in performance year-over-year, we also considered requiring IOTA participants to owe downside-risk payments to CMS if their final performance score was at or below 40 for more than one PY, starting from PY 1, potentially giving IOTA participants a similar phased-in, or, rather, ramp-up, opportunity to adjust and improve before downside-risk payments kick in. We considered this option to be unnecessary and operationally complex, particularly as it would function in a similar way as our proposed approach from a phasing-in standpoint. We also considered adjusting the $2,000 fixed, risk-based payment amount for PYs 2–6; however, we believe a fixed amount would provide greater transparency to IOTA participants on financial risk and model implementation experience would better inform if this approach would be necessary.

We sought comment on our proposed downside risk payment calculation formula, and alternatives considered.

The following is a summary of the comments received on our proposed downside risk payment calculation formula, alternatives considered, and our responses:

Comment: A couple commenters suggested that we should increase the maximum downside risk payment. To encourage greater engagement from IOTA participants who are likely to struggle, a commenter recommended two changes: (1) Lowering the proposed final performance score threshold for the downside risk payment zone in PY 2 from less than 40 points to less than 20 points, and (2) Increasing the maximum downside risk payment amount to −$4000 per Medicare kidney transplant. The commenter believed that by decreasing the likelihood of failure but increasing its consequences, CMS would ensure that only IOTA participants who actively choose not to engage would face negative repercussions. Another commenter proposed increasing the maximum downside risk payment for each Medicare kidney transplant from the proposed $2,000 to $3,750. They believed the IOTA Model incentives must be substantial enough to capture the attention of transplant hospital and health system administrators, while the downside risk payment should be high enough to motivate IOTA participants to avoid incurring it entirely.

Another commenter pointed out that IOTA participants who abstain from participating risk termination from the model and may face penalties. Specifically, under the proposed rule, terminated IOTA participants could be liable for a penalty in the PY of their termination and may have to refund any upside risk payments from previous PYs. The commenter further noted that IOTA participants could view the penalty as a low-cost way to avoid accountability in the model through 2031. The commenter also pointed out that the shrinking pool of Medicare FFS patients, has the same effect of reducing both upside risk payments and downside risk payments. Based on these concerns, the commenter urged CMS to reconsider how it calculates downside risk payments, and at minimum, to apply the same $8,000 fixed amount used in the upside risk payment calculation to the downside risk payment calculation.

Response: We thank the commenters for their suggestions. In putting downside risk in the model, we are attempting to incentivize improved performance on the IOTA metrics, while also attempting to not make the model too punitive for IOTA participants. As such, we will be finalizing the maximum downside risk payment as proposed. We will evaluate the effects of our payment methodology and may propose raising the maximum downside risk payment if we are not seeing the level of change that we are hoping for in future notice and comment rule making

Comment: A commenter urged that CMS make the proposed maximum downside risk payment proportional to the proposed maximum upside risk payment.

Response: The model was designed with asymmetric upside and downside risk in recognition of the benefits provided by transplant to the Medicare Trust Fund and the desire of CMS to not be overly punitive in a mandatory model. We plan to test out the effects of a $2,000 maximum downside risk payment to assess its effects on the metrics in the IOTA Model. Based on the results, we may consider increasing the maximum downward amount in future notice and comment rule making.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing the proposed provision for calculating the downside risk payment at § 512.430(b)(3), without modification.. We also note that we are finalizing, as proposed, the definition of Medicare kidney transplants at § 512.402 without modification, as described and finalized in section III.C.6(b) of this final rule.

(c) Neutral Zone

If, in PY 1, an IOTA participant's final performance score was below 60 points, or if, in PYs 2–6, an IOTA participant's final performance score was between 41 and 59 (inclusive), we proposed that the final performance score, as described in section III.C.6.c.(1). of this final rule, would qualify the IOTA participant for the neutral zone, where no upside risk payment or downside risk payment would apply. As such, in a PY where an IOTA participant's final performance score falls in the neutral zone, no money would be paid to the IOTA participant by CMS, nor would money be owed by the IOTA participant to CMS.

We sought comment on our proposed neutral zone.

Comment: Multiple comments urge constricting the neutral zone to make it more likely that an IOTA participant would receive a positive or negative payment adjustment.

Response: To begin the model, we plan to keep the neutral zone as designed. Our goal is to recognize both excellent performers and those that fall far below expectations and ensure that only those IOTA participants receive a positive or negative payment adjustment. We will evaluate how many IOTA participants fall into the neutral zone and consider constriction in the future.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing the neutral zone provisions at § 512.430(b)(2) as proposed without modification.

(3) Payments Operations and Timelines

After the end of each PY, CMS would assess each IOTA participant's performance in accordance with section III.C.5. of this final rule and calculate performance-based payments in accordance with the methodology specified in section III.C.6.c. of this final rule. We proposed to define this process as ''preliminary performance assessment and payment calculations.''

We proposed that CMS would conduct and calculate preliminary performance assessment and payment calculations at least 3 to 6 months after the end of each PY to allow for sufficient Medicare kidney transplant claims runout. We proposed that CMS would notify IOTA participants of their preliminary model performance assessment, including the IOTA participant's score for each metric within the achievement domain, efficiency domain, and quality domain and the final performance score, and payment calculations with respect to any applicable upside risk payment or downside risk payment, at least 5 to 9 months after the end of each PY, allowing for a two-to-three month period for CMS to conduct calculations after the claims runout period. We proposed that a 30-day notification period between preliminary and final calculations would apply, giving IOTA participants 30 days to review preliminary data and calculations and request targeted reviews, as described in section III.C.6.c.(4). of this final rule. This 30-day notification period would also be intended to provide IOTA participants with advance notice of forthcoming performance-based payments before upside risk payments or demand letters for downside risk payments would be issued by CMS. We also proposed that CMS would notify IOTA participants of their model performance assessment and payment calculations in a form and manner determined by CMS, such as letters, email, or model dashboard. We proposed that CMS would notify the IOTA participant of their final performance score and any associated upside risk payment or downside risk payment at least 30 days after notifying the IOTA participant of their preliminary model performance assessment and payment calculations.

We proposed that after CMS notifies the IOTA participant of their final performance score and any associated upside risk payment and by a date determined by CMS, CMS would issue the upside risk payment to the tax identification number (TIN) on file for the IOTA participant in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS).

We proposed that after CMS notifies the IOTA participant of their final performance score and any associated downside risk payment and by a date determined by CMS, CMS would issue a demand letter to the TIN on file in PECOS for the IOTA participant for downside risk payments owed to CMS, with a payment due date of at least 60 days after the date on which the demand letter is issued. We proposed that the demand letter would include details on model performance, the downside risk payment, and how payments would be made to CMS.

Rather than the proposed lump-sum payment and demand letter approach, we also considered making the upside risk payments and downside risk payments to IOTA participants in the form of Medicare FFS claim adjustments. The benefit of this approach would be that upside risk payments and downside risk payments, which are retrospective, would be applied prospectively and spread out over a 12-month period, so that a transplant hospital would not need to pay back to CMS a large sum of monies owed all at once. However, we believe that this approach would delay model payments and collection of monies owed to CMS. We also consider this approach to be disruptive to standard claims processing systems and operationally complex, with more opportunities for error and less flexibility to correct errors in a timely manner.

We sought comment on our proposed payment operations and timeline and alternative considered.

The following is a summary of the comments received on our proposed payment operations and timeline, alternative considered and our responses:

Comment: We received a comment approving of the payment operations timeline process.

Response: We appreciate that comment and plan to finalize as proposed.

Comment: We received a comment urging an alternative methodology for potential repayments that would allow an IOTA participant to mitigate the downside risk payments owed to CMS through an agreed upon strategy of process and performance improvement across various metrics.

Response: We see this as an interesting idea, but ultimately decided to go with the proposed strategy of repayment to recognize the large

behavioral incentives of wanting to avoid writing a check to repay CMS. We also see that this process is inherently present in the model, given that performance on model measures resets each year. We also recognize that there is no downside risk in PY 1, and we hope that any IOTA participants with a final performance score below 40 who would otherwise have had to pay downside risk payments to CMS can use that as an opportunity for process improvement to avoid having to make downside risk payments for PY 2.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing these provisions without modification at § 512.430(d). We are also finalizing the definition of preliminary performance assessment and payment calculations at § 512.402, without modification.

(4) Targeted Review

We believe that CMS calculation errors are possible, and therefore IOTA participants should be able to dispute the results of calculations.

Thus, upon receipt of CMS issued notifications of preliminary performance assessment and payment calculations, as described in section III.C.6.c(3) of this final rule, we proposed at § 512.434 that IOTA participants may appeal via a ''targeted review process,'' defined as the process in which an IOTA participant could dispute performance assessment and payment calculations made, and issued, by CMS.

We proposed at § 512.434(a) that an IOTA participant would be able to request a targeted review for one or more calculations made and issued by CMS within the preliminary performance assessment and payment calculations. We proposed at §§ 512.434(a)(1) and (2) that an IOTA participant would be able to request a targeted review for CMS consideration if—

- The IOTA participant believes an error occurred in calculations due to data quality or other issues; or
- The IOTA participant believes an error occurred in calculations due to misapplication of methodology.

We proposed at § 512.434(b)(1) that an IOTA participant would be required to submit a targeted review request within 30 days, or another time period as specified by CMS, of receiving its preliminary performance assessment and payment calculations from CMS. We also proposed at § 512.434(b)(2) that the request would require supporting information from the IOTA participant, in a form and manner specified by CMS. The 30-day window to appeal generally aligns with the length of time we have finalized for submitting appeals in other CMS models, such as the ETC Model, as well as under the Hospital VBP Program, and we believed would allow ample time for IOTA participants to separately review CMS calculations.

We proposed at § 512.434(c) that the targeted review process would not provide IOTA participants the ability to dispute policy and methodology, as it would be limited to the dispute of calculations. Specifically, we proposed at § 512.434(c)(1) that CMS would not consider targeted review requests regarding, without limitation, the following:

- The selection of the kidney transplant hospital to be an IOTA participant.
- The attribution of IOTA waitlist patients and the attribution of IOTA transplant patients to the IOTA participant, or to any other kidney transplant hospital selected for participation in the IOTA Model, or to any kidney transplant hospital not selected for participation in the IOTA Model.
- The methodology used for determining the achievement domain, efficiency domain, and quality domain.
- The methodology used for calculating and assigning points for each metric within the achievement domain, efficiency domain, and quality domain.
- The methodology used for calculating the payment amount per Medicare kidney transplant paid to an IOTA participant.

We proposed § 512.434(c)(2) that a targeted review request that includes one or more of the exclusions under § 512.434(c)(1) could still be reviewed by CMS, given that all remaining considerations of the request meet all other criteria for consideration by CMS.

Upon receipt of a targeted review request from an IOTA participant, we proposed at § 512.434(d)(1) that CMS would conduct an initial assessment and final assessment of the targeted review. We believed that this proposal would be in line with other CMS models.

The CMS targeted review initial assessment would determine if the targeted review request met the targeted review requirements and contained sufficient information to substantiate the request. If the request was not compliant with the requirements or required additional information, CMS would follow up with IOTA participants to request additional information in a form and manner determined by CMS. Any additional information that CMS requests from an IOTA participant would be due to CMS within 30 days of CMS's request, also in a form and manner determined by CMS. An IOTA participant's non-responsiveness to the request for additional information from CMS could result in the closure of the targeted review request.

In a final assessment, CMS would determine whether it erred in a calculation, as disputed by the IOTA participant.

CMS's correction of an error may delay the date of payment of an IOTA participant's upside risk payments or downside risk payments.

We stated in the proposed rule that were a calculation error to be found as a result of an IOTA participant's targeted review request, we would notify the IOTA participant within 30 days of any findings in a form and manner determined by CMS and resolve and correct the error and discrepancy in the amount of the upside risk payment or downside risk payment in a time and manner as determined by CMS.

We proposed at § 512.434(d)(2) that targeted review decisions made by CMS would be final, unless submitted by the IOTA participant or CMS for a CMS Administrator review. We also proposed to include the reconsideration determination process as outlined in proposed § 512.190 in the IOTA Model.

We noted that if an IOTA participant has regular Medicare FFS claims issues or decisions that it wishes to appeal (that is, issues during the model performance period with Medicare FFS that are unrelated to the model performance and payment calculations and payments), then the IOTA participant should continue to use the standard CMS procedures. Section 1869 of the Act provides for a process for Medicare beneficiaries, providers, and suppliers to appeal certain claims and decisions made by CMS.

We sought comment on our proposals regarding the process by which an IOTA participant could request a targeted review of CMS calculations.

The following is a summary of the comments received on our proposals regarding the process by which an IOTA participant could request a targeted review of CMS calculations and our responses:

Comment: We received a comment approving of the proposed targeted review process.

Response: We that the commenter for their support and plan to finalize these provisions as proposed.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing the provisions for the proposed targeted review process at 512.434(d) without

modification. We are also finalizing the definition of targeted review process at § 512.402, with a minor technical correction to update the cross reference.

(5) Extreme and Uncontrollable Circumstances

As we stated in the proposed rule, events may occur outside the purview and control of the IOTA participant that may affect their performance in the model (89 FR 43518). In the event of extreme and uncontrollable circumstances, such as a public health emergency, we proposed that CMS may reduce the downside risk payment, if any, prior to recoupment by an amount determined by multiplying the downside risk payment by the percentage of total months during the PY affected by an extreme and uncontrollable circumstance, by the percentage of attributed patients who reside in an area affected by the extreme and uncontrollable circumstance. We proposed to address only the downside risk payment under this policy, as we wish to mitigate the harm to entities due to extreme and uncontrollable circumstances. We considered applying this policy to upside risk payments and final performance scores in the neutral zone, but we believe that IOTA participants that have been able to achieve model success do not need to be made whole by this policy.

We proposed at § 512.436(a)(1) to apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred, and the affected areas, during the PY. We chose the Quality Payment Program to align across Innovation Center models and CMS policy. We proposed at § 512.436(a)(2) that CMS has the sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of attributed patients residing in affected areas for the IOTA participant.

We requested comment on our extreme and uncontrollable circumstances policy and whether the determinations by the Quality Payment Program that an extreme and uncontrollable circumstance have occurred should apply to IOTA participants.

We did not receive any comments on this policy and therefore are finalizing these provisions without modification at § 512.436.

7. Data Sharing

a. General

As discussed in the proposed rule, we expect that IOTA participants would work toward independently identifying and producing their own data, through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of services.

To assist IOTA participants in this process, we proposed to provide IOTA participants with certain beneficiary-identifiable data for their Medicare beneficiaries who are attributed patients, upon request. We anticipated that IOTA participants would use this data to better assess transplant readiness and post-transplant outcomes. We also proposed to provide certain aggregate data that has been de-identified in accordance with the HIPAA Privacy Rule, 45 CFR 164.514(b), as discussed later in this section, for the purposes of helping IOTA participants understand their progress towards the model's performance metrics.

Specifically, subject to the limitations discussed in this final rule, and in accordance with applicable law, including the HIPAA Privacy Rule, we proposed that CMS may offer an IOTA participant an opportunity to request certain Medicare beneficiary-identifiable data and reports as discussed in section III.C.7.b of this final rule. We proposed that CMS would share this beneficiary-identifiable data with IOTA participants on the condition that the IOTA participants, their IOTA collaborators, and other individuals or entities performing functions or services related to the IOTA participant's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information, and comply with the terms of the data sharing agreement described in this section of the final rule.

We proposed that the beneficiary-identifiable claims data described in section III.C.7.b of this final rule would omit individually identifiable data for Medicare beneficiaries who have opted out of data sharing with the IOTA participant, as described in section III.C.7.c of this final rule. We also noted that, for the beneficiary-identifiable claims data, we would exclude information that is subject to the regulations governing the confidentiality of substance use disorder patient records (42 CFR part 2) from the data shared with an IOTA participant.

b. Beneficiary-Identifiable Data

(1) Legal Authority To Share Beneficiary-Identifiable Data

As discussed in the proposed rule, we believe that an IOTA participant may need access to certain Medicare beneficiary-identifiable data for the purposes of evaluating its performance, conducting quality assessment and improvement activities, conducting population-based activities relating to improving health or reducing health care costs, or conducting other health care operations listed in the first or second paragraph of the definition of ''health care operations'' under the HIPAA Privacy Rule, 45 CFR 164.501.

We proposed that, subject to providing the beneficiary with the opportunity to decline data sharing as described in section III.C.10.a of this final rule, and subject to having a valid data sharing agreement in place, an IOTA participant may request from CMS certain beneficiary identifiable claims for attributed patients who are Medicare beneficiaries.

As stated in section III.C.7(b)(1) of the proposed rule, we recognized there are sensitivities surrounding the disclosure of individually identifiable (beneficiary-specific) health information, and several laws place constraints on the sharing of individually identifiable health information. For example, section 1106 of the Act generally bars the disclosure of information collected under the Act unless a law (statute or regulation) permits the disclosure. Here, we noted that, in this circumstance, the HIPAA Privacy Rule would allow for the proposed disclosure of individually identifiable health information by CMS.

We noted in the proposed rule that under the HIPAA Privacy Rule, covered entities (defined in 45 CFR 160.103 as health care plans, health care providers that submit certain transactions electronically, and health care clearinghouses) are barred from using or disclosing individually identifiable health information (called ''protected health information'' or PHI) in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule, without the individual's authorization (89 FR 43518). The Medicare FFS program, a ''health plan'' function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI without an individual's authorization. IOTA participants are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they or their agents electronically engage in one or more HIPAA standard transactions, such as for claims,

eligibility or enrollment transactions. In light of these relationships, as discussed in the proposed rule, we believe that the proposed disclosure of the beneficiary-identifiable data under the IOTA Model would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for ''health care operations'' purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed, the PHI pertains to that relationship, and the recipient will use the PHI for a ''health care operations'' function that falls within the first two paragraphs of the definition of ''health care operations'' in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

The first paragraph of the definition of health care operations includes ''conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines,'' and ''population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination.'' The second paragraph of the definition of health care operations includes ''evaluating practitioner and provider performance'' (45 CFR 164.501).

Under our proposal, IOTA participants would be using the data on their patients to evaluate the performance of the IOTA participant and other providers and suppliers that furnished services to the patient, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their patients. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as ''health care operations'' under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. Hence, as discussed in the proposed rule, we believe that this provision is extensive enough to cover the uses we would expect an IOTA participant to make of the beneficiary-identifiable data and would be permissible under the HIPAA Privacy Rule. Moreover, our proposed disclosures would be made only to HIPAA covered entities that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of ''health care operations.'' Finally, the proposed disclosures would be limited to beneficiary-identifiable data that we believe would meet HIPAA requirements in 45 CFR 164.502(b) to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when Federal agencies maintain systems of records by which information about an individual is retrieved by use of one of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act generally prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

As described in the proposed rule, ''routine uses'' are an exception to this general principle (89 FR 43576). A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. As we stated in the proposed rule, we believe that the proposed data disclosures are consistent with the purposes for which the data discussed in this rule was collected, and, thus, would not run afoul of the Privacy Act, provided we ensure that an appropriate Privacy Act system of records ''routine use'' is in place prior to making any disclosures. The systems of records from which CMS would share data are the Medicare Integrated Data Repository (IDR) and the Health Resources and Services Administration (HRSA) Organ Procurement and Transplantation Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR) Data System. We stated in the proposed rule that we believe that the proposed data disclosures are consistent with the purposes for which the data were collected and may be disclosed in accordance with the routine uses applicable to those records.

We proposed that CMS would share the following beneficiary-identifiable lists and data with IOTA participants that have submitted a formal request for the data. Under our proposal, the request must be submitted on an annual basis in a manner and form and by a date specified by CMS. The request also would need to identify the data being requested and include an attestation that (A) the IOTA participant is requesting this beneficiary-identifiable data as a HIPAA covered entity or as a business associate, as those terms are defined at 45 CFR 160.103, to the IOTA participant's providers and suppliers who are HIPAA covered entities; and (B) the IOTA participant's request reflects the minimum data necessary for the IOTA participant to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501. In addition, we proposed that IOTA participants who request this data must have a valid and signed data sharing agreement in place, as described in more detail later in this section. We proposed that we would make available beneficiary-identifiable data as described in section III.C.8.b. of this final rule for IOTA participants to request for purposes of conducting health care operations that fall within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of their attributed patients who are Medicare beneficiaries. We explained that we believe that access to beneficiary-identifiable claims data would improve care coordination between IOTA participants and other health care providers. Patients can spend months in between their visits to the kidney transplant hospital at which they are listed, and the post-transplant period is critical to transplant success. We stated that we believe that improved care coordination would improve outcomes and keep patients engaged in their care.

We also proposed that IOTA participants limit the request for beneficiary-identifiable claims data to Medicare beneficiaries whose name appears on the quarterly attribution list who have been notified in compliance with section III.C.10.a. of the proposed rule, and who did not decline having their claims data shared with the IOTA participant, as proposed in section III.C.7.d. of the proposed rule. Finally, we proposed that CMS would share beneficiary identifiable data with an IOTA participant on the condition that the IOTA participant, its IOTA collaborators, and other individuals or entities performing functions or services related to the IOTA participant's activities, observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and comply with the terms of the data sharing agreement described in section III.C.7.f. of the proposed rule.

The following is a summary of the public comments we received on the proposal to share certain beneficiary-

identifiable data with IOTA participants and our responses:

Comment: A couple of commenters expressed support for the proposal to share certain beneficiary-identifiable data with IOTA participants. The commenters indicated that these data would enable IOTA participants to identify their patient populations, plan and improve care, and gauge the quality of post-acute care providers.

Response: We thank the commenters for their support for the proposal to share certain beneficiary-identifiable data under this model and concur with the stated benefits for IOTA participants in receiving such data.

After consideration of the comments received, we are finalizing at § 512.440 our proposals to share certain beneficiary-identifiable claims data with IOTA participants as proposed with minor technical corrections. Specifically, we made a minor technical correction at § 512.440(a) to clarify that, as stated in this section and in the proposed rule, CMS shares certain beneficiary-identifiable data as described in § 512.440(b) and certain aggregate data as described in § 512.440(c) with IOTA participants regarding attributed patients who are Medicare beneficiaries and performance under the model. We also made a minor technical correction at § 512.440(b)(3) to correct a grammatical error.

(2) Quarterly Attribution Lists

We proposed that this beneficiary-identifiable data would include, for the relevant PY, a beneficiary attribution report, shared quarterly, that would include a list of attributed patients and patients who have been de-attributed from the IOTA participant. We proposed that the report would include at least the following information for each attributed patient: the attribution year the attributed patient became attributed to the IOTA participant; the effective date of the attributed patient's attribution to the IOTA participant; the effective date of the patient's de-attribution from the IOTA participant and the reason for such removal (if applicable); and the attributed patient's data sharing preferences made pursuant to section III.C.7.d. of this final rule. We proposed that CMS may include additional information at its discretion in any of the quarterly attribution reports as data becomes available. Such data may include information from the SRTR or OPTN on waitlist status or transplant status.

We requested comment on whether such additional information would be beneficial to IOTA participants or whether this information is best accessed by the IOTA participant through other means.

We received no public comments on these proposals and therefore are finalizing this provision as proposed to provide quarterly attribution lists to IOTA participants at § 512.440(b)(5)(i), without modification.

(3) Beneficiary-Identifiable Claims Data

In section III.C.7(b)(3) of the proposed rule, we proposed to offer certain beneficiary-identifiable claims data to IOTA participants no later than one month after the start of each PY, in a form and manner specified by CMS. We proposed that IOTA participants may retrieve this data at any point during the relevant PY and that it would include, at a minimum—

- Three years of historical Parts A, B, and D claims data files for attributed patients who are Medicare beneficiaries for 36 months immediately preceding the effective date of the Medicare beneficiary's attribution to the IOTA participant;
- Monthly Parts A, B, and D claims data files specified for attributed patients who are Medicare beneficiaries; and
- Monthly Parts A, B, and D claims data files for Medicare beneficiaries who have been de-attributed from the IOTA participant for claims with a date of service prior to the date the Medicare beneficiary was removed from attribution to the IOTA participant.

We proposed that CMS would omit from the beneficiary-identifiable claims data any substance use disorder patient records subject to 42 U.S.C. 290dd–2 and the implementing regulations at 42 CFR part 2.

We stated that we believe these data elements would consist of the minimum data element necessary for IOTA participants to effectively manage the care of Medicare beneficiaries who are attributed patients. Specifically, this data would allow IOTA participants to coordinate care across the continuum as Medicare beneficiaries who are attributed patients transition from IOTA waitlist patients to IOTA transplant patients.

We requested comments on this proposal to share beneficiary-identifiable claims data with IOTA participants at § 512.440(b)(5)(ii).

The following is a summary of the public comments we received on the proposal to share beneficiary-identifiable claims data with IOTA participants and our responses:

Comment: A few commenters expressed support for the proposal to share certain beneficiary-identifiable claims data with IOTA participants. A commenter indicated that more data delivered more frequently to ensure timely opportunity to influence performance would be more beneficial.

Response: We thank the commenters for their support for the proposal to share certain beneficiary-level data under this model and will strive to deliver data to IOTA participants in a timely manner to assist in their performance under the model. We have committed to a minimum data set and this specific frequency to allow for potential operational challenges or delays.

After consideration of the comments received, we are finalizing our regulation at § 512.440 (b)(5)(ii) to share certain beneficiary-identifiable claims data with IOTA participants, without modification.

c. Minimum Necessary Data

We proposed IOTA participants must limit their beneficiary-identifiable data requests to the minimum necessary to accomplish a permitted use of the data. We proposed the minimum necessary Parts A and B data elements may include, but are not limited to, the following data elements:

- Medicare beneficiary identifier (ID).
- Procedure code.
- Gender.
- Diagnosis code.
- Claim ID.
- The from and through dates of service.
- The provider or supplier ID.
- The claim payment type.
- Date of birth and death, if applicable.
- Tax Identification Number (TIN).
- National Provider Identification (NPI).

We proposed the minimum necessary Part D data elements may include, but are not limited to, the following data elements:

- Beneficiary ID.
- Prescriber ID.
- Drug service date.
- Drug product service ID.
- Quantity dispensed.
- Days supplied.
- Brand name.
- Generic name.
- Drug strength.
- TIN.
- NPI.
- Indication if on formulary.
- Gross drug cost.

We requested comment and feedback on the minimum beneficiary-identifiable claims data necessary for IOTA participants to request for purposes of conducting permissible health care operations purposes under this model.

We received no public comments on our proposed provisions regarding the minimum beneficiary-identifiable claims data necessary for IOTA participants to request for purposes of conducting permissible health care operations under this model. Thus, we are finalizing the proposed provisions at § 512.440(b)(ii)(6), without modification.

d. Medicare Beneficiary Opportunity To Decline Data Sharing

As described in section III.C.10.a. of this final rule, we proposed that Medicare beneficiaries must receive notification about the IOTA Model. We also proposed that Medicare beneficiaries must be given the opportunity to decline claims data sharing, and instructions on how to inform CMS directly of their preference.

We proposed that Medicare beneficiaries would be notified about the opportunity to decline claims data sharing through the proposed notifications discussed in section III.C.10.a. of this final rule. We proposed that these notifications must state that the IOTA participant may have requested beneficiary identifiable claims data about the Medicare beneficiary for purposes of its care coordination and quality improvement work and/or population-based activities relating to improving health or reducing health care costs, and inform the Medicare beneficiary how to decline having his or her claims information shared with the IOTA participant in the form and manner specified by CMS. We proposed that Medicare beneficiary requests to decline claims data sharing would remain in effect unless and until a beneficiary subsequently contacts CMS to amend that request to permit claims data sharing with IOTA participants.

As discussed in the proposed rule (89 FR 43577), we proposed that Medicare beneficiaries may not decline to have the aggregate, de-identified data proposed in section III.C.7.f. of the proposed rule shared with IOTA participants. We also proposed that Medicare beneficiaries may not decline to have the initial attribution lists, quarterly attribution lists, or annual attribution reconciliation list as proposed in section III.C.4.b.(2)., b.(3). and b.(4). of this final rule shared with IOTA participants. We noted that, in accordance with 42 U.S.C. 290dd–2 and its implementing regulations at 42 CFR part 2, CMS would not share beneficiary identifiable claims data relating to the diagnosis and treatment of substance use disorders under this model.

In section III.C.7(d) of the proposed rule, we noted that the proposed opt out provisions discussed in this section would relate only to the proposed sharing of beneficiary-identifiable data between the Medicare program and the IOTA participant under the IOTA Model, and were in no way intended to impede existing or future data sharing under other authorities or models.

We requested comment and feedback on our proposed policies to enable Medicare beneficiaries to decline data sharing under the model.

We received no comments on this proposal and therefore are finalizing the proposed provisions to allow Medicare beneficiaries to decline data sharing at § 512.440(b)(ii)(7), without modification.

e. Data Sharing Agreement

(1) General

As noted in section III.C.7.a. of this final rule, we proposed that, prior to receiving any beneficiary-identifiable data, IOTA participants would be required to first complete, sign, and submit—and thereby agree to the terms of—a data sharing agreement with CMS. We proposed that under the data sharing agreement, the IOTA participant would be required to comply with the limitations on use and disclosure that are imposed by HIPAA, the applicable data sharing agreement, and the statutory and regulatory requirements of the IOTA Model. We also proposed that the data sharing agreement would include certain protections and limitations on the IOTA participant's use and further disclosure of the beneficiary-identifiable data and would be provided in a form and manner specified by CMS. Additionally, we proposed that an IOTA participant that wishes to retrieve the beneficiary identifiable-data would be required to complete, sign, and submit to CMS a signed data sharing agreement at least annually. We stated that we believe that it is important for the IOTA participant to complete and submit a signed data sharing agreement at least annually so that CMS has up-to-date information that the IOTA participant wishes to retrieve the beneficiary-identifiable data and information on the designated data custodian(s). As described in greater detail later in this section, we proposed that a designated data custodian would be the individual(s) that an IOTA participant would identify as responsible for ensuring compliance with all privacy and security requirements and for notifying CMS of any incidents relating to unauthorized disclosures of beneficiary-identifiable data.

As described in section III.C.7.e(1) of the proposed rule, CMS believes it is important for the IOTA participant to first complete and submit a signed data sharing agreement before it retrieves any beneficiary-identifiable data to help protect the privacy and security of any beneficiary-identifiable data shared by CMS with the IOTA participant. We noted that there are important sensitivities surrounding the sharing of this type of individually identifiable health information, and CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with IOTA participants would be further protected in an appropriate fashion.

We solicited public comment on our proposal to require that the IOTA participant agree to comply with all applicable laws and terms of the data sharing agreement as a condition of retrieving beneficiary-identifiable data, and on our proposal that the IOTA participant would need to submit the signed data sharing agreement at least annually if the IOTA participant wishes to retrieve the beneficiary-identifiable data.

The following is a summary of the public comments we received on the proposals to define the IOTA data sharing agreement, to require compliance with the terms of the IOTA data sharing agreement as a condition of retrieving the beneficiary-identifiable data, and to require submission of the IOTA data sharing agreement at least annually, and our responses to these comments:

Comment: A couple commenters expressed support and appreciation for the proposed protections surrounding the sharing of beneficiary-identifiable data with IOTA participants. A commenter reiterated that any data sharing should be conducted in a manner that protects patient privacy and allows all points of care to maximize lessons learned and implement quality improvement activities. A commenter expressed concern with prohibiting disclosures to an individual practitioner in a treatment relationship with the attributed patient who is a Medicare beneficiary, or that practitioner's business associates.

Response: We thank the commenters for their support and agree that appropriate protections must be ensured in the sharing of beneficiary-identifiable data. We are finalizing that the data sharing agreement will include a provision prohibiting any further disclosure, not otherwise required by law, of the beneficiary-identifiable data to anyone who is not a HIPAA covered entity or business associate, as defined

in 45 CFR 160.103, or who is not an individual practitioner in a treatment relationship with the attributed patient who is a Medicare beneficiary, or that practitioner's business associates. Therefore, this provision would not prohibit data sharing with a covered entity or its business associate for treatment purposes. Such a prohibition would be similar to that imposed by CMS in other models tested under section 1115A of the Act, such as the KCC Model, in which CMS shares certain beneficiary-identifiable data with model participants for their health care operations.

CMS will include this prohibition in the data sharing agreement because there exist important legal and policy limitations on the sharing of the beneficiary-identifiable data and must carefully consider the ways in which and reasons for which CMS would provide access to this data for purposes of the IOTA Model.

After consideration of the comments received, for the reasons set forth in this rule, we are finalizing at § 512.440(b)(8) the provisions of the data sharing agreement as an agreement entered into between the IOTA participant and CMS that includes the terms and conditions for any beneficiary-identifiable data shared with the IOTA participant under § 512.440, without modification. In addition, we are finalizing at § 512.440(b)(8)(i) the proposal that the IOTA participant would need to submit the signed IOTA data sharing agreement at least annually if the IOTA participant wishes to retrieve the beneficiary-identifiable data from CMS.

We are also finalizing at § 512.440(b)(8)(ii) the proposed requirement that the IOTA participant agree to comply with all applicable laws and the terms of the IOTA data sharing agreement as a condition of retrieving the beneficiary-identifiable data.

(2) Content of the Data Sharing Agreement

We proposed that CMS would share the following beneficiary-identifiable data with IOTA participants that have requested the data and have a valid data sharing agreement in place, as described in more detail later in this section. We proposed that an IOTA participant that wishes to receive beneficiary-identifiable data for its attributed patients who are Medicare beneficiaries must also agree to certain terms, namely: (1) to comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations at 45 CFR part 160 and part 164, subparts A and E, and the requirements of the proposed IOTA Model; (2) to comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the data sharing agreement; (3) to contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the IOTA participant, including all IOTA collaborators, to the same terms and conditions with the IOTA participant is itself bound in its data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the IOTA participant under the IOTA Model; and (4) that if the IOTA participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may: (A) deem the IOTA participant ineligible to retrieve the beneficiary-identifiable data under paragraph (b) of this section for any amount of time; (B) terminate the IOTA participant's participation in the IOTA Model under § 512.466; and (C) subject the IOTA participant to additional sanctions and penalties available under the law.

We stated in the proposed rule that CMS believes these proposed terms for sharing beneficiary-identifiable data with IOTA participants are appropriate and important, as CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with IOTA participants would be further protected by the IOTA participant, and any business associates of the IOTA participant, in an appropriate fashion.

CMS sought public comment on the additional privacy, security, breach notification, and other requirements that we would include in the data sharing agreement. CMS has these types of agreements in place as part of the governing documents of other models tested under section 1115A of the Act and in the Medicare Shared Savings Program. In these agreements, CMS typically requires the identification of data custodian(s) and imposes certain requirements related to administrative, physical, and technical safeguards relating to data storage and transmission; limitations on further use and disclosure of the data; procedures for responding to data incidents and breaches; and data destruction and retention. These provisions would be imposed in addition to any restrictions required by law, such as those provided in the HIPAA privacy, security, and breach notification regulations. We noted that these data sharing agreement provisions would not prohibit the IOTA participant from making any disclosures of the data otherwise required by law.

CMS also sought public comment on what specific disclosures of the beneficiary identifiable data might be appropriate to permit or prohibit under the data sharing agreement. For example, we stated that CMS was considering prohibiting, in the data sharing agreement, any further disclosure, not otherwise required by law, of the beneficiary-identifiable data to anyone who is not a HIPAA covered entity or business associate, as defined in 45 CFR 160.103, or to an individual practitioner in a treatment relationship with the attributed patient who is a Medicare beneficiary, or that practitioner's business associates. Such a prohibition would be similar to that imposed by CMS in other models tested under section 1115A of the Act in which CMS shares certain beneficiary-identifiable data with model participants for their health care operations.

We noted in the proposed rule that CMS is considering these possibilities because there exist important legal and policy limitations on the sharing of the beneficiary-identifiable data and CMS must carefully consider the ways in which and reasons for which we would provide access to this data for purposes of the IOTA Model. We stated that CMS believes that some IOTA participants may require the assistance of business associates, such as contractors, to perform data analytics or other functions using this beneficiary-identifiable data to support the IOTA participant's review of their care management and coordination, quality improvement activities, or clinical treatment of IOTA beneficiaries. CMS also believes that this beneficiary-identifiable data may be helpful for any HIPAA covered entities who are in a treatment relationship with the IOTA beneficiary.

We sought public comment on how an IOTA participant might need to, and want to, disclose the beneficiary-identifiable data to other individuals and entities to accomplish the goals of the IOTA Model, in accordance with applicable law.

Under our proposal, the data sharing agreement would include other provisions, including requirements regarding data security, retention, destruction, and breach notification. For example, as stated in section III.C.7 of the proposed rule, we were considering including, in the data sharing agreement, a requirement that the IOTA

participant designate one or more data custodians who would be responsible for ensuring compliance with the privacy, security and breach notification requirements for the data set forth in the data sharing agreement; various security requirements like those found in participation agreements for other models tested under section 1115A of the Act, but no less restrictive than those provided in the relevant Privacy Act system of records notices; how and when beneficiary-identifiable data could be retained by the IOTA participant or its downstream recipients of the beneficiary-identifiable data; procedures for notifying CMS of any breach or other incident relating to the unauthorized disclosure of beneficiary-identifiable data; and provisions relating to destruction of the data. We stated that these are only examples and are not the only terms CMS would potentially include in the data sharing agreement.

We solicited public comment on this proposal to impose certain additional requirements in the IOTA data sharing agreement related to privacy, security, data retention, breach notification, and data destruction.

We received no comments on this proposal and therefore are finalizing these proposed provisions at § 512.440(b)(8), without modification.

f. Aggregate Data

We proposed that CMS would share certain aggregate performance data with IOTA participants in a form and manner to be specified by CMS. This aggregate data would be de-identified in accordance with HIPAA requirements at 45 CFR 164.514(b) and would include, when available, transplant target data.

We proposed that, for the relevant PY, CMS would provide aggregate data to the IOTA participant detailing the IOTA participant's performance against the transplant target, as described in section III.C.5.c.(2). of this final rule.

We sought comment and feedback on our proposal to share aggregate data with IOTA participants.

We received no comments on this proposal and therefore are finalizing the proposed provisions at § 512.440(c) without modification.

8. Other Requirements

a. Transparency Requirements

(1) Publication of Patient Selection Criteria for Kidney Transplant Evaluations

Transplant hospitals are currently required to use written patient selection criteria in determining a patient's suitability for placement on the waitlist or a patient's suitability for transplantation per the CoP (see 42 CFR 482.90). If the transplant hospital performs living donor transplants, the transplant hospital must use written donor selection criteria to determine the suitability of candidates for donation.[289] The patient selection criteria must ensure fair and non-discriminatory distribution of organs, and the program must document in the patient's medical record the patient selection criteria used.[290] Prior to placement on the transplant hospital's waitlist, a prospective transplant candidate must receive a psychosocial evaluation, if possible.[291] Before a transplant hospital places a transplant candidate on its waitlist, the candidate's medical record must contain documentation that the candidate's blood type has been determined.[292] In addition, when a patient is placed on a hospital's waitlist or is selected to receive a transplant, the transplant hospital must document in the patient's medical record the patient selection criteria used.[293] Currently, the transplant hospital must also provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by the patient or a dialysis facility. For living donor selection, the transplant hospital's living donor selection criteria must be consistent with the general principles of medical ethics.[294] [295] Transplant hospitals 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.[296]

Available data and studies demonstrate that disparities exist for patients in underserved communities who seek or are referred for, or are evaluated for a transplant and who eventually are placed on a transplant waitlist and receive an organ transplant (89 FR 43579).[297] For instance, the data has shown that White patients are more likely than Black patients to be referred for organ transplant, while Black patients are less likely than White patients to be referred for transplant evaluation.[298] Racial disparities also exist in transplant wait listing, even after correcting for SDOH.[299] In addition, there are sex and gender disparities in access to the kidney transplant waitlist, with men more likely to have access compared to women.[300] Finally, a recent article in the Journal of the American Medical Association considers how transplant programs factor patient financial resources into waitlist decisions.[301] The authors' review of several studies suggested that socioeconomically deprived patients were proportionally less likely to be selected for placement on a waitlist for an organ transplant. They suggested, based on the strong and consistent associations between race and poverty, that ''withholding transplants from those with inadequate financial resources equates to an example of structural racism in the health care system.'' We refer readers to the numerous additional studies regarding disparities in organ transplantation and organ donation that are cited throughout the final rule.

In section III.C.8.a(1) of the proposed rule, to improve transparency for those looking to gain access to a transplant waitlist in the transplant program evaluation processes, we proposed to require IOTA participants to publicly post, on a website, their patient selection criteria for evaluating patients for addition to their kidney transplant waitlist by the end of PY 1. We proposed to finalize this requirement only if it is not redundant with other

---

[289] *https://www.ecfr.gov/current/title-42/section-482.90.*

[290] Ibid.

[291] Ibid.

[292] Ibid.

[293] Ibid.

[294] OPTN. (n.d.). *OPTN Policies—Living Donation, Chapter 14. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

[295] AMA Council on Ethical and Judicial Affairs. (2019). AMA Code of Medical Ethics' Opinions on Organ Transplantation. *AMA Journal of Ethics, 14*(3), 204–214. *https://doi.org/10.1001/virtualmentor.2012.14.3.coet1-1203.*

[296] *https://www.ecfr.gov/current/title-42/section-482.90.*

[297] 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.*

[298] Epstein, A.M., Ayanian, J.Z., Keogh, J.H., Noonan, S.J., Armistead, N., Cleary, P.D., Weissman, J.S., David-Kasdan, J.A., Carlson, D., Fuller, J., Marsh, D., & Conti, R.M. (2000). Racial Disparities in Access to Renal Transplantation—Clinically Appropriate or Due to Underuse or Overuse? *New England Journal of Medicine, 343*(21), 1537–1544. *https://doi.org/10.1056/nejm200011233432106.*

[299] Ng, Y.-H., Pankratz, V.S., Leyva, Y., Ford, C.G., Pleis, J.R., Kendall, K., Croswell, E., Dew, M.A., Shapiro, R., Switzer, G.E., Unruh, M.L., & Myaskovsky, L. (2019). Does Racial Disparity in Kidney Transplant Wait-listing Persist After Accounting for Social Determinants of Health? *Transplantation,* 1. *https://doi.org/10.1097/tp.0000000000003002.*

[300] Ahern, Patrick et al. Sex Disparity in Deceased-Donor Kidney Transplant Access by Cause of Kidney Disease. 2021. *Clinical Journal of the American Society of Nephrology.* 16 (2) 241–250, *https://cjasn.asnjournals.org/content/16/2/241.*

[301] Wadhwani, S.I., Lai, J.C., & Gottlieb, L.M. (2022). Medical Need, Financial Resources, and Transplant Accessibility. *JAMA, 327*(15), 1445. *https://doi.org/10.1001/jama.2022.5283.*

HHS guidance. We also considered requiring that IOTA participants update their selection criteria at a certain frequency to ensure that attributed patients have the most up to date information. However, we are unsure what cadence of update would be most appropriate.

We solicited public comments on this proposal and on how often the selection criteria should be updated by the IOTA participant.

The following is a summary of the comments received on our proposal to require IOTA participants to publicly post their patient selection criteria for kidney transplant waitlist candidates on a website and the frequency at which updating this information should occur and our responses:

Comment: Many commenters stated they support the publication of patient selection criteria for kidney transplant evaluations. A commenter specified that it could help reduce distrust around organ transplant decisions.

Response: We thank the commenters for their support. We agree that posting patient selection criteria for evaluating patients for addition to a waitlist will help reduce distrust about organ transplant decisions.

Comment: A commenter suggested that patient selection criteria should be posted in common languages of the local community and that any written materials be delivered in patients' preferred language.

Response: We thank the commenter for their suggestion. We agree that public facing patient selection criteria for evaluating patients for addition to a waitlist should be made available in local languages and should be compliant with regulations requiring patients to have written information in their preferred language.

Comment: Numerous commenters were concerned about the impact of publicly posted patient selection criteria on their patients. A commenter was concerned that overwhelming patients with selection criteria published on a public-facing website is not patient-centered, does not promote autonomy and impacts the patient-provider relationship. Similarly, a commenter conveyed their concern that there is a significant risk of misinterpretation of the selection criteria by referring providers in the community and patients, which may decrease referrals. Additionally, a commenter was concerned that public disclosure of waitlist selection criteria that only applies to IOTA participants, does not help patients who may live in a region with access to more than one kidney transplant hospital.

Response: We thank the commenters for their responses and concerns. We believe that providing patient selection criteria for evaluating patients for addition to a waitlist publicly creates transparency for both patients and for their referring nephrologists. Referring nephrologists have more patient contact than a transplant nephrologist at time of referral, and therefore are key in referring patients for kidney transplant evaluation and in having the ability to guide the patient to the kidney transplant hospital that may be most ideal for the patient. With the overwhelming amount of information that a kidney transplant patient learns during their multi-hour initial transplant evaluation, we believe that resources to encourage early transplant discussions between a referring nephrologist and patient can create opportunities for a more fruitful evaluation experience for the patient. This may also open communication between transplant nephrologists and referring nephrologists. We agree that potential transplant candidates and selection criteria can be extremely complex and vary on a case-by-case basis; however, we believe that providing general expectations for kidney transplant candidacy is by no means unreasonable and can make the evaluation process more efficient. For example, if a kidney transplant hospital will definitively not transplant a patient with a certain co-morbidity, whereas another kidney transplant hospital may, this can be extremely helpful for a patient to know before taking off from work or a dialysis session and organizing transportation or both for a kidney transplant hospital that is hundreds of miles away. Sometimes it may take months to schedule specialist visits or preventative health screenings, needed for transplant waitlisting. Listing selection waitlist criteria can help patients anticipate what appointments they may need to schedule. We understand there are ''gray'' areas of candidacy and subsequently have not created prescriptive requirements for patient selection lists.

Public-facing patient selection criteria for evaluating patients for addition to a waitlist allows patients to understand general expectations earlier in their transplant evaluation journey, ensures keeping criteria up to date, and provides greater access and autonomy to patients. While non-participants of the IOTA Model are not mandated by this requirement, we suggest that other kidney transplant hospitals follow suit.

Comment: A commenter was concerned that public posting of kidney transplant waitlist selection criteria policy is redundant since it is already available publicly through groups such as CMS, HRSA, UNOS and OPTN.

Response: We thank the commenter for their concern. While 42 CFR 482.90 already requires documentation of selection criteria within the patient's medical record upon placement on the waiting list, it does not specify the need for publicly posting patient selection criteria decisions.[302] Currently, there is not a centralized site listing all transplant programs' selection criteria. Patients have access to their medical records through patient portals or can alternatively access a hard copy of their records by request. We believe it is also important that the patient has access to this information before the visit. We also believe that public facing listing criteria provides greater access to patients who may not be able to easily access their patient portal, reducing disparities.

Comment: A commenter suggested that CMS would need to closely monitor this transparency requirement and penalize IOTA participants that do not comply.

Response: Thank you for your responses regarding monitoring for compliance. We agree that long term there will need to be monitoring and auditing to ensure that IOTA participants are compliant with listing their selection criteria. We are hopeful to receive further feedback throughout and after PY 1 to modify this requirement to be as specific as is reasonable to ensure compliance. Additionally, we are hopeful that there is opportunity to have a collective site, which would feature all IOTA participants' selection criteria on one website.

Comment: A couple of commenters were concerned by the differences in self-reported listing criteria versus characteristics of patients that are ultimately listed. One of these commenters recommended that CMS focus on the data of waitlist patients. A commenter stated that CMS should also consider the differences in the criteria for accepting a referral, evaluating the patient, and listing the patient.

Response: We thank the commenters for their feedback. We recognize there are limitations in mandating public posting of selection criteria and that there is discordance between self-reported kidney transplant hospital listing criteria and the actual characteristics of their listed patients for transplant. While we acknowledge that

[302] *https://www.ecfr.gov/current/title-42/section-482.90.*

it may be challenging to package numerous patient co-morbidities into an easily digestible and reasonable list of selection criteria, we believe that exercising a requirement to bring transparency to selection criteria will also assist kidney transplant hospitals in tailoring those criteria and be as specific as possible. To avoid deterring referrals of possible transplants, we have not considered posting referral requirements at this time and will not do so without further consideration and input from the transplant community. We do, however, believe it would be greatly beneficial for kidney transplant hospitals to outline the difference between referral, evaluation and listing on their website and additionally review this information during every patient's transplant evaluation visit.

Comment: A couple of commenters included their support for the development of a centralized, standardized way to present information about transparency requirements such as selection criteria and bypass filters. A commenter further recommended that patient education surrounding this transparency information should be created by a centralized group (such as OPTN or SRTR) to reduce kidney transplant hospital burdens.

Response: We agree that a centralized location for waitlist selection criteria and organ offer acceptance criteria would be ideal and are hopeful that the transplant community can move toward a database that is accessible to patients and providers or both that will provide this information; however, we do not believe that this is necessary for PY 1 for IOTA participants. We believe it is reasonable and not overly burdensome to request IOTA participants to post their selection criteria on their website. We intend to continue discussions about a centralized database for patient waitlist selection criteria and will consider this for future rulemaking,

Comment: A commenter suggested that IOTA participants should be required to conduct targeted outreach to non-citizens and other underserved communities to provide clarifications and education on transplant.

Response: We appreciate the commenter's feedback. We believe it is in the purview of individual IOTA participants to have outreach events to serve their community. Currently the IOTA Model does not outline the topic of educational outreach; however, we will take this comment into consideration for future rulemaking since patient education is extremely important throughout the continuum of kidney care and is needed to expand equal access to transplant. Additionally, please note that community outreach would be a potential opportunity for IOTA participant to consider as part of the voluntary health equity plans in the IOTA Model, as reviewed in section III.C.8.c of this final rule.

Comment: A commenter requested that CMS provide flexibility regarding the frequency of updating waitlist selection criteria. A couple of commenters were concerned with balancing accurate information with resource burden.

Response: We appreciate the commenter's response regarding frequency of waitlist criteria updates and type of information included. Beyond requirements previously outlined in 42 CFR 482.90, we have not provided specific requirements that IOTA participants must include regarding listing practices.[303] We do, however, expect and trust that IOTA participants are acting in good faith to provide accurate waitlisting criteria and specific details, when possible. While we did not propose a specific cadence as to how frequently IOTA participants should be required to update their selection criteria after PY 1, we will take these comments into consideration during future rulemaking. We do not believe that requesting a public online posting about patient waitlist selection criteria by the end of PY 1, is overly burdensome to IOTA participants, as IOTA participants are already expected to provide these criteria in patient waitlist documentation. We are finalizing this requirement as originally proposed in section III.C.8.a(1) of the proposed rule, for PY 1, without modification.

Comment: A commenter suggested that waitlist selection criteria should include specific details such as absolute contraindications of IOTA participants (for example, BMI limits), whether there are financial reserve requirements, and if other factors such as psychiatric or psychosocial factors impact listing.

Response: We thank the commenters for their recommendations. Beyond requirements previously outlined in 42 CFR 482.90, CMS has not provided specific requirements that IOTA participants must include regarding listing practices.[304] We do believe, though, that if IOTA participants have a list of absolute versus relative contraindications for their patients, it would be beneficial to make patients and referring nephrologists aware of these concerns.

While we agree that it could be helpful for patients to understand specific psychosocial and psychiatric requirements, we believe that this could be challenging given the multidimensional evaluation that is completed during transplant evaluation and the complexity of understanding each individual's situation. Additionally, psychiatric and psychosocial diagnoses can be fluid, and we would not want to discourage patients from transplant evaluation, particularly since they may learn about helpful resources during the evaluation. A goal of the IOTA Model is to reduce disparities in kidney transplant, and we believe that listing granular psychosocial or psychiatric requirements could be contradictory to these goals.

Listing specific financial requirements could be helpful if transplant programs have absolute cutoffs for transplant recipients; however, if patients do not initially meet financial requirements, transplant program resources (financial counselor, social workers) may be able to help that patient create a financial plan to meet that requirement. We will take this comment into consideration for future iterations of the IOTA Model and encourage additional feedback from kidney transplant hospitals during PY 1.

Comment: A commenter suggested it may be easier if CMS created a list of criteria that each IOTA participant needs to address in the selection criteria.

Response: We thank you for your comment. As previously mentioned in section III.C.8.a.(1) of this final rule, 42 CFR part 428.90 does outlines basic requirements for kidney transplant evaluation.[305] Currently, we believe that being prescriptive beyond these requirements prevents kidney transplant providers and kidney transplant hospitals from creating selection criteria applicable to risk level they believe is appropriate based on their resources and their community. We believe that including referring nephrologists in conversations regarding specific listing criteria could be helpful, however, we are not mandating this.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing the requirement that IOTA participants must publicly post their patient selection waitlist criteria on a website by the end of PY 1 at § 512.442(a), without modification. We intend to use

[303] *https://www.ecfr.gov/current/title-42/section-482.90.*

[304] *https://www.ecfr.gov/current/title-42/section-482.90.*

[305] *https://www.ecfr.gov/current/title-42/section-482.90.*

future rulemaking to determine the cadence of updating this website and patient selection criteria. For IOTA participants who choose to post their patient selection criteria for evaluating patients for addition to their kidney transplant waitlist early in the PY 1, we also encourage them to update their criteria again, should it change throughout the year.

(2) Transparency Into Kidney Transplant Organ Offers

As discussed in section III.C.8.a(2) of the proposed rule, those active on a kidney transplant waitlist may receive organ offers at any time. However, there is currently no requirement for providers to discuss organ offers with their patients. A provider may decline an organ offer for any number of reasons; however, declining without disclosing the rationale with the patient may miss an important opportunity for shared decision-making.

In section III.C.8.a(2) of the proposed rule, 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 for 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. We are not proposing to prescribe the method of this notification but would require that the medical record reflect that the patient received this information and the method by which it was delivered (for example, mail, email, medical appointment, internet portal/dashboard, etc.). We proposed that this information must be shared with the IOTA waitlist patient who is a Medicare beneficiary, and should be shared, where deemed appropriate, with their nephrologist or nephrology professional, to provide the opportunity for questions and clarification of information.

Organ offer filters are a tool that transplant programs can use to bypass organ offers they would not accept. Offer filters were tested during two pilot programs and released nationally in January 2022.[306] In section III.C.8.a(2) of the proposed rule, we proposed that IOTA participants would be required to review transplant acceptance criteria and organ offer filters with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist. We proposed that this review may be done on an individual basis in a patient visit, via phone, email, or mail. We believed that sharing this information with the patient would offer an opportunity for shared decision-making between the patient and IOTA participants and may increase the patient's quality of care. We proposed that Medicare beneficiaries would be able to decline this review with the IOTA participant, as some may not wish to have this information. We anticipated that the Medicare beneficiary may decline this review during their next provider visit or over the phone.

We solicited public comment on whether an alternative frequency of sharing of organ offers with the Medicare beneficiary is more appropriate. We also solicited comment on whether there is a more suitable timeframe and frequency for addressing acceptance criteria with attributed patients. Per 42 CFR 482.94(c), and 482.102(a) and (c), kidney transplant hospitals currently review these criteria with patients upon patient request. Our goal was to provide a balance of transparency and patient engagement in this process without being overly prescriptive or burdensome. We also recognized that there are beneficiaries on the waitlist who may not be eligible to receive an organ offer for multiple years, so we sought feedback on whether this requirement should be limited to beneficiaries who have received or are likely to receive an organ offer in the next year.

The following is a summary of comments we received on our proposal to (1) require monthly notifications to Medicare beneficiaries receiving organ offers who are IOTA waitlist patients about number of organs declined and the rationale for the decline and to (2) require review of transplant acceptance criteria and organ offer filters with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist and our responses:

Comment: Commenters expressed concern about the proposed transparency into kidney transplant organ offers provision, which would require IOTA participants to inform, on a monthly basis, IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf and the reason(s) for the decline. Specifically, commenters felt this would impose a significant administrative burden on IOTA participants. Some of these commenters were concerned that notifying waitlisted Medicare patients of organ offer declines and the reasons for those declines would be burdensome, costly, and of questionable value. This was seen as at odds with the IOTA Model's quality and efficiency domain goals and was seen as disproportionately burdensome to smaller transplant hospitals. Commenters also noted that the provision does not account for the clinical and administrative resources needed to review the high volume of organ declines across all waitlisted individuals. This could divert resources away from patient care. Furthermore, a commenter stated that patient care groups are more interested in data on time-to-transplant and likelihood of receiving a transplant, which are already publicly available.

Response: We thank the commenters for their concerns. Due to the many concerns received, we recognize that monthly notification to Medicare beneficiaries regarding volume and reason for organ decline could be very burdensome to IOTA participants and their staff in PY 1 since this is a new initiative and there is not current infrastructure or database resources to aid in minimizing burden on IOTA participants. We believe 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, we will not be finalizing our regulation at proposed § 512.442(b), which required that Medicare beneficiaries on the IOTA participant's waitlist be notified monthly about organ offers. 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 rulemaking.

Comment: A commenter expressed concern that discussions about organ offer filters, while allowing patients to influence decisions, may not provide providers with enough data to fully inform and engage patients. For example, providers may lack information on how these filters impact wait times. The commenter suggested this could prevent patients from believeing they can meaningfully contribute to shared decision-making.

[306] *Optimizing Usage of Kidney Offer Filters—OPTN.* (n.d.). *Optn.transplant.hrsa.gov.* Retrieved March 11, 2023, from *https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/optimizing-usage-of-kidney-offer-filters/.*

Response: We appreciate the commenter's feedback and subsequently recognize that our proposal to require IOTA participants to review transplant acceptance criteria and organ offer filters with their IOTA waitlist patients who are Medicare beneficiaries requires clarification. We also acknowledge that explaining the organ offer filter itself may not promote the same outcome as sharing the impact of organ offer acceptance criteria. In light of this, we are finalizing our review of selection criteria and organ offer filters provisions with slight modifications. Specifically, we are finalizing at § 512.442(c) that IOTA participants must review transplant organ offer acceptance criteria (rather than acceptance criteria and organ offer filters) with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist. Additionally, we are removing all references to organ offer filters.

Regarding the commenter's concern that they may not have enough information to share with patients regarding organ offer filters, we believe that generally discussing organ offer acceptance criteria is a first step in increasing patient's awareness about why certain organs may or may not be accepted at a particular transplant program. As IOTA participants may choose to analyze data to better understand ideal organ offer filters, these findings can be used as supporting evidence when explaining to beneficiaries why their transplant program for example, may not accept kidney transplant with a particular cold ischemic time.

Comment: A commenter agreed that organ offer filters should be reviewed with patients at least every 6 months to strengthen their original education.

Response: We thank the commenter for their support. We recognize that explaining the organ offer filter itself may not promote the same outcome as sharing the organ offer acceptance criteria. Subsequently, we are finalizing and clarifying that reviewing organ offer acceptance criteria (rather than the filter itself), with IOTA waitlist patients who are Medicare beneficiaries at least every 6 months, will meet this requirement. We suspect that IOTA participants will have more frequent changes in their organ offer filters during the first few years of the IOTA Model as kidney transplant hospitals optimize their practices.

Comment: A commenter expressed support for reviewing transplant organ offer acceptance criteria with IOTA waitlist patients who are Medicare beneficiaries every six months.

Response: We thank the commenter for their support.

Comment: A commenter argued that operationalizing the proposed transparency into kidney transplant organ offers would be more efficiently achieved by directing the OPTN to develop a patient portal. This portal would allow patients to view their own organ offer filters and organ decline statistics online, rather than requiring each IOTA participant to develop their own reporting system. The commenter emphasized that this approach would promote patient engagement, education, and accountability at kidney transplant hospitals, as patients would be able to access the information themselves. Overall, the commenter felt this would be both more efficient and more effective in achieving the desired result of increased transparency.

Response: We thank the commenter for their valuable suggestions. We recognize the importance of delivering consistent messages about patient education and matters such as organ offer filters, organ offer acceptance criteria, and declined organ offers. As we continue our collaborative work with OTAG, we will carefully consider these recommendations. Additionally, we encourage IOTA participants to discuss this proposal within the IOTA Model learning system. We direct readers to section III.C.15 of this final rule for a full discussion on the IOTA Model learning system.

Comment: A few commenters suggested reviewing acceptance criteria and declined organ offers during key timeframes, such as transplant evaluation, annual waitlist visits, or when first listed on the waiting list. For example, a commenter, while supporting transparency, encouraged upfront communication with patients about organ offer practices during evaluation and annual visits. As an alternative, this commenter recommended that IOTA participants be required to educate patients on the organ offer process, declines, and patients' right to information—with IOTA participants providing specific details upon patient request.

Another commenter expressed support for sharing organ offer filters and transplant acceptance criteria with patients. However, the commenter recommended IOTA participants review these details with patients when they are first listed on the waiting list, and update patients if any changes are made. For patients who want information about declined offers, the commenter suggested discussing their transplant acceptance criteria periodically as they receive that information. For patients who opt out of declined offer details or do not discuss them with the IOTA participant, the commenter recommended an annual review of their organ offer filters and transplant acceptance criteria (or at the time of re-evaluation, whichever comes first). Additionally, the commenter supported CMS's proposal to allow patients to decline this review altogether. Lastly, a commenter suggested that IOTA participants review organ offers received with their waitlisted patients during annual or biannual waitlist visits. The commenter asserted that this would give patients the chance to discuss any changes to their organ offer acceptance criteria and ask their provider questions directly.

Response: We appreciate the valuable feedback from commenters. Although many kidney transplant hospitals see their waitlisted patients at least annually, this practice is inconsistent. Waitlist patient visit frequency can also vary depending on the patient's active or inactive waitlist status. To better inform patients about organ offers and the reasons for declining them, beyond the initial evaluation and waitlist clinic visits, we proposed more frequent patient notifications, as described in section III.C.8.a(2) of this final rule. In light of the comments received, we recognize that successfully implementing an organ offer notification process will require more extensive planning. Therefore, we will not be finalizing the transparency into kidney transplant organ offer provisions at proposed § 512.442(b). However, we remain committed to increasing communication and engagement with patients on the kidney transplant waitlist.

Regarding the proposed review of acceptance criteria and organ offer filters transparency requirement, as described in section III.C.8.a(2) of this final rule, we believe it is important to finalize this provision for several key reasons: (1) it should not create a significant administrative burden; (2) it provides the building blocks of education for IOTA waitlist patients; and (3) due to other themes of the IOTA Model that may impact organ offer filter use, we believe reviewing organ offer acceptance criteria with patients every 6 months is appropriate. As mentioned in comment responses in this section, we also recognize that explaining organ offer filters with waitlisted patients may not promote the same outcome as reviewing organ offer acceptance criteria. As such, we will be finalizing our proposed review of acceptance

criteria provision at § 512.442(c) with minor technical corrections. Specifically, we added ''organ offer'' to transplant acceptance criteria that must be disclosed and removed all references to ''organ offer filters''. Additionally, we will 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.

Comment: Several commenters recommended organ offer inclusion or exclusion criteria for the proposed transparency into kidney transplant organ offer provision. The commenters believed the proposed notification requirement should be limited to minimize administrative burden. Their suggested inclusion criteria were: (1) if the patient is the primary recipient, or (2) if the kidney offer is declined by one hospital but used by another. Their suggested exclusion criteria included: (1) kidneys outside a 250-mile radius, (2) discarded kidneys, (3) kidney organ offers that were declined by all kidney transplant hospitals on the match run, or (4) patients removed from a waitlist before a monthly reporting period concluded. Several commenters replied about the inclusions and exclusions from notification requirements.

Response: We appreciate the commenters' feedback. We reiterate that, as mentioned in comment responses in this section, we are not finalizing the proposed transparency organ offer notification provision at proposed § 512.442(b). We aim to engage with the transplant community to identify conditions that should be captured in exclusion criteria, to inform future rulemaking pertaining to transparency into kidney transplant organ offers.

Comment: Some commenters expressed concerns about the proposed transparency into kidney organ offers provision. In particular, they worried it may require IOTA participants to carefully manage how information is shared. The commenters also mentioned that additional security controls may be needed to prevent donor information from being shared with recipients. Another commenter stated the transparency into kidney transplant organ offers provision should include specific details on donor kidney offers, to protect patient privacy and prevent increased use of suboptimal kidneys. Additionally, a commenter cited safeguarding patients' legal and ethical rights to informed consent and autonomy as paramount. Lastly, a couple commenters suggested alternatives, such as only discussing declined organ offer review at the programmatic level among transplant program providers, or using a collaborative model with some privacy walls while sharing select information with patients or the public.

Response: We thank the commenters for sharing their concerns and suggestions about patient privacy. We agree that patient privacy of donors and potential recipients is paramount and believe that safeguarding patients' rights to informed consent and autonomy is imperative. However, in response to the comments we received, as mentioned in comment responses in this section, we are not finalizing the proposed transparency into kidney transplant organ offers provision, requiring IOTA participants to inform IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf, at proposed § 512.442(b).

Comment: A few commenters expressed concerns that the transparency into kidney transplant organ offers provisions are overly complex and unnecessary. Moreover, a commenter felt these requirements are redundant, as transplant programs must already provide patients access to SRTR data resources that publicly disclose information about their organ offer acceptance rates.

Response: We thank the commenters for expressing their concerns. While we acknowledge that the new processes needed to meet the proposed transparency into kidney transplant organ offer provisions (89 FR 43580) would initially be labor-intensive or technologically challenging, we maintain that these requirements are important and increase patient awareness.

Additionally, we disagree that the proposed transparency into kidney transplant organ offers requirements are redundant programmatic requirements of providing SRTR data; providing generalized organ offer acceptance rate ratio data is very different from providing direct notification to a patient about an organ offer that was declined on their behalf. However, based on commenter feedback, we recognize the complexities of notifying patients about declined organ offers. While we are not finalizing the proposed transparency into kidney transplant organ offers provisions at proposed § 512.442(b), we remain interested in exploring alternative ways to promote transparency for kidney transplant waitlist patients.

Comment: A couple commenters urged CMS to consider how the proposed transparency into kidney transplant organ offers provision could inadvertently impact the behavior of kidney transplant hospitals. For example, a commenter noted that the proposed organ offers notification requirement emphasizes the importance of discussing organ offer declines with patients, which is crucial for informed decision-making. However, the commenter expressed concern that the focus on organ offer declines could deter the use of higher-risk organs, ultimately reducing the number of viable transplants, or kidney transplant hospitals might potentially offer the organ despite it not being the best fit for the recipient.

Response: We appreciate the commenters concerns regarding the proposed transparency into kidney transplant organ offers provision, as outlined at § 512.442(b) in the proposed rule. We agree that this provision may impact provider and staff awareness of consistent kidney transplant offers that are being declined, which could affect filtering practices. Increasing patient-staff conversations not only creates opportunities for patients to stay better informed about their care, but also allows transplant staff to stay up to date on a patient's waitlist status and recent medical changes. We view more frequent patient interactions as a positive behavioral change. As previously discussed in comment responses in this section, we are not finalizing the transparency into kidney transplant organ offers provision at proposed § 512.442(b), however, we continue to be committed to working with the transplant community to identify alternative transparency opportunities for kidney transplant waitlist patients.

Comment: A couple of commenters stated that CMS should consider alternate ways to promote transparency, including incorporating the voices of consumers, including patients in community councils, inviting community members to serve on boards and equipping patients with data about kidney transplant hospitals so they can make informed decisions.

Response: We appreciate the commenters' feedback. We believe direct dialogue and advocacy between patients and kidney transplant hospitals can enhance communication, helping these hospitals better understand areas needing improvement, such as information gaps and lack of transparency. HHS intends to make organ offer information more easily accessible for patients who are on the waiting list, to minimize administrative burden. While these concepts are not incorporated into the IOTA Model, we believe they are concepts that kidney

transplant hospitals should further consider.

Comment: A commenter expressed concern that the proposed organ offer notification requirement would create disparities, as it would only apply to Medicare patients and IOTA participants.

Response: We thank the commenter for sharing their concern that the transparency into kidney transplant organ offers provision, as proposed, would create disparities because only Medicare patients and IOTA patients would be subject to the requirement. The Innovation Center's authority in this proposed rule only extends to Medicare beneficiaries, which is why we only proposed that it apply to IOTA waitlist patients who are Medicare beneficiaries. However, as mentioned in comment responses in this section, we are not finalizing the proposed transparency into kidney transplant organ offers provision, requiring IOTA participants to inform IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf, at proposed § 512.442(b).

Comment: A few commenters urged CMS to reduce the administrative burden on IOTA participants imposed by the proposed transparency requirements. Suggestions included leveraging existing technology and data, evaluating the administrative and financial impacts, and providing IOTA participants with the necessary resources to successfully implement the proposed transparency requirements. Several commenters supported a centralized process to achieve transparency, facilitated by CMS or UNOS/OPTN, which could include standardized patient-specific reports using existing OPTN information, an application programming interface, or a patient portal.

Response: We agree that a future centralized online resource could improve patient access and reduce administrative burdens for kidney transplant hospitals by providing patient organ offer notifications. HHS intends to make organ offer information more easily accessible in the future, to minimize administrative burden for transplant programs. As previously mentioned in this section, we will not be finalizing the proposed transparency into kidney transplant organ offers provision at proposed § 512.442(b). We aim to examine the administrative and financial challenges involved in notifying patients of organ offers, and explore how technology can be used to reduce this administrative burden.

Comment: A commenter expressed support for informing patients on the transplant waitlist, if a patient is active on the transplant waiting list and eligible to receive organ offers, when those organ offers have been declined on their behalf. The commenter argued that transparency should not be compromised for these patients. Additionally, the commenter urged CMS to hold IOTA participants accountable for communicating a patient's waitlisting status when: (1) a patient becomes inactive, including explaining the reasons why and possible solutions to regaining active status, if feasible; and, (2) a patient regains active waitlisting status after being inactivated.

Response: We thank the commenter for their support of the proposed transparency into kidney transplant organ offers provision. However, as mentioned in comment responses in this section, we will not be finalizing this provision at this time. We still believe that it is important to increase transparency for kidney transplant waitlist patients regarding the volume of organ offers received and declined on their behalf while on the waiting list. We also value the commenter's recommendation to hold IOTA participants accountable for communicating a patient's waitlisting status. We acknowledge the importance of patient awareness regarding their waitlist status, an aspect that is often overlooked. Additionally, we recognize the significant number of inactive patients on the waiting list, many of whom may be unaware of their inactive status or the reasons behind it. This aligns with our goal of promoting transparency and SDM between the patient and IOTA participants. We will consider the commenter's suggestion along with the public comments on the proposed transparency requirements and may make future proposals during the course of the model test.

Comment: A commenter asserted that CMS could achieve the goals of the proposed transparency into kidney transplant organ offers requirements without significantly increasing the administrative burden on participating kidney transplant hospitals. Instead of the proposed requirements, the commenter recommended that CMS mandate a discussion about offer screening during the patient consent process. Additionally, the commenter suggested that participating kidney transplant hospitals be required to document these discussions, include them in their records, or address them with patients during evaluations or once they are placed on the waitlist.

Response: We thank the commenters for their suggestions. However, we are concerned that organ offer discussions at the time of initial evaluation for transplant candidacy, while a good start, is insufficient for patient education. Patients often feel overwhelmed by the extensive transplant education they receive when first considering a kidney transplant. This can be especially challenging for those who have recently been diagnosed with kidney disease, making the prospect of transplant seem particularly daunting. While comprehensive education at the time of evaluation and waitlist is important, we believe patients would benefit from more frequent, ongoing guidance about organ offers, acceptance criteria, and deferral tendencies throughout the listing process. As previously mentioned in comment responses in this section, we will not be finalizing the transparency into kidney transplant organ offers provisions at proposed § 512.442(b) at this time due to the aforementioned concerns. We are committed to exploring new ways to increase transparency in collaboration with the transplant community.

Comment: A commenter highlighted that they previously urged CMS to mandate greater transparency about the risk aversion of transplant hospitals and surgeons. This transparency, the commenter argued, would allow patients to find a transplant hospital that aligns with their personal risk tolerance. While the commenter welcomed the IOTA Model's proposal to include two such transparency policies, they strongly disagreed with the policies being part of a demonstration rather than a nationwide requirement.

Response: We thank the commenter for their support. The Innovation Center is limited in exercising authority specific to Medicare beneficiaries and is unable to create nationwide mandates for patients with all types of insurance coverage. However, successful Innovation Center models are often reviewed and discussed as opportunities to expand to the nation through other policies. While we are not finalizing the proposed transparency into kidney transplant organ offers requirements at § 512.442(b) of the proposed rule, we hope that transplant hospitals who are not selected to participate in the IOTA Model will consider integrating IOTA Model concepts into their kidney transplant hospital.

Comment: A few commenters mentioned that modifications to the transparency requirements were needed or that the transparency into kidney transplant offers provision should be

eliminated entirely but did not provide further suggestions or justification.

Response: We thank the commenters for the feedback. We are interested in understanding the commenters' specific modification suggestions and invite them to provide further details in the future.

Comment: Several commenters supported the provision requiring transparency into kidney transplant organ offers, with some of them specifying that providing Medicare beneficiaries the option to be informed about organs that were declined on their behalf supports increased communication and shared decision making between patients and providers. One of these commenters also believed that increasing transparency would hold kidney transplant hospitals accountable, drive ongoing improvements across the transplant system and help eliminate health disparities.

Response: We greatly appreciate the commenters' words of support; however, we are not finalizing this provision. We look forward to future feedback as we work to create transparency requirements that are not unduly burdensome. We remain invested in evaluating alternative transparency opportunities with the transplant community.

Comment: A couple of commenters conveyed concerns with barriers to patient receipt of transparency notifications, stating that IOTA participants may use automated notifications in place of the meaningful communication that would be required to provide quality care. A commenter was specifically concerned by technical barriers reaching patients, such as outdated contact information.

Response: We agree these are valid challenges with all types of patient communications. While automated notifications may be preferred by some patients, it may further worsen disparities in already vulnerable populations. We recognize that disparities in access to technology can limit certain patients, making phone calls or other methods of contact necessary. Patient portals may provide a source of quick, easy access to information; however, this can prevent real-time discussions. This concern is one of the reasons that we will not be finalizing the proposed transparency into kidney transplant organ offers provision as proposed at § 512.442(b). We look forward to engaging with kidney transplant hospitals to identify and share efficient yet appropriate methods for equitably notifying and making patients aware of declined kidney transplant organ offers, without creating disparities for those who may not have access to technology.

Comment: Several commenters suggested CMS modify the transparency into kidney transplant organ offers provision, which would require IOTA participants to inform, on a monthly basis, IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf and the reason(s) for the decline. Specifically, they suggested that organ offer declines should be shared only to a certain sequence number in the match run, keeping the information to a manageable amount and focusing on organs that the patient had a reasonable likelihood of receiving. Suggested notification thresholds included the top 5, 100, 150, or 200 matches of the match run, or only when the organ was used for a transplant candidate positioned further down on the waiting list. For example, a commenter suggested that since a quarter of organ offers are accepted at or after having been offered to 73 transplant candidates, organ offer declines should be shared with transplant candidates up to match run sequence 150, which is about 73 doubled. Alternatively, the commenter suggested that CMS could mirror the SRTR definition of a hard-to-place kidney (100) and cap sharing the organ offer decline information at transplant candidates who were lower than 100 in the match run sequence.

Response: We thank the commenters for their suggestion to only share organ offer declines to a certain sequence number in the match run and modify the provision requiring transparency into kidney transplant organ offers. Since we are not currently finalizing this provision, as mentioned in comment responses in this section, we will keep this feedback in mind as we consider alternatives in future rulemaking.

Comment: Many commenters requested clarification on the proposed transparency into kidney transplant organ offer provision requiring IOTA participants, for months in which an organ offer is made, to inform IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf. For example, a commenter wanted to know what deliverable(s) CMS expects in order to validate compliance with this requirement. Another commenter asked CMS to clarify what constitutes an organ offer decline. The commenter stated that due to the complexity of the organ offer system and variability in OPO behavior, a transplant hospital may receive an organ offer before many transplant hospitals ahead of them have reviewed and declined it. As a result, the commenter was concerned that a transplant hospital may review an offer when they do not actually have the opportunity to transplant the organ, as they are not the ''primary'' recipient. The commenter also noted a recent significant increase in expedited organ placement, where an OPO can send an organ to a hospital that is not next in line. Additionally, the commenter pointed out that an IOTA waitlist patient may have a declined offer but then be removed from the waitlist due to transplant or other reasons before the monthly report period ends; potentially creating uncertainty for IOTA participants on whether to notify the IOTA waitlist patient in such scenarios. Furthermore, the commenter suggested that different IOTA participants may define the required reporting differently, and that some declined offers may be more relevant to IOTA waitlist patients than others.

A few commenters sought clarity on which organ offers and declines would be included in this requirement. For instance, a commenter asked if the requirement would cover only primary offers, which occur sporadically, or all offers regardless of match quality—potentially numbering in the hundreds per month. This same commenter also raised questions about whether hospital representatives or physicians (who may be unaffiliated private practitioners) should have discussions about organ offers with IOTA waitlist patients, and how IOTA participants could effectively communicate complex clinical information to non-clinical patients without causing strife or animosity, as patients and families often misunderstand or underestimate the risks of poorly matched organs and recipients.

Response: We thank the commenters for their questions and feedback. As mentioned in comment responses in this section, we are not finalizing the proposed transparency into kidney transplant organ offers provision, requiring IOTA participants to inform IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf. However, as we continue to consider ways to increase transparency, we will consider this feedback in future rulemaking.

Comment: A few commenters expressed concerns that the new transparency requirements into kidney transplant organ offers may have unintended consequences. They worried the requirements could encourage IOTA participants to accept

lower-quality kidneys, offer kidneys that are not the best fit for recipients, or deter the use of higher-risk organs. Additionally, a commenter noted that monthly reporting on declined kidney offers does not account for the increasing reliance on out-of-sequence allocation for high-risk kidneys that may otherwise be discarded.

Many commenters emphasized the importance of allowing transplant surgeons, who are knowledgeable about each patient's unique circumstances, to exercise discretion in making clinical decisions without facing pressure to accept suboptimal organs or penalties for denying them. They warned that restricting this discretion could undermine trust between the transplant program and patients. One of these commenters also expressed concern that transplant programs are worried about patient dissatisfaction and potential legal actions due to declinations. This is because patients might falsely be given the sense that they would have had the option of accepting a kidney that is not clinically acceptable.

Response: We thank the commenters for their feedback. The proposed provisions for transparency into declined kidney transplant offers is not intended to question a provider's medical judgment or expertise. Rather, it aims to better inform patients about whether they are receiving offers and the reasons behind any declines. For instance, if a size mismatch between the recipient and donor kidney prompts deferring the transplant to an alternative recipient, the transparency requirement should not impact that clinical decision. However, we proposed that IOTA waitlist patients who are Medicare beneficiaries be made aware of any declined offers and the rationale, allowing them the opportunity to ask questions and understand the process. The goal of this proposed transparency requirement is to facilitate more open patient-provider discussions about the kidney transplant process before undergoing the major, life-altering procedure—not to erode trust or encourage litigation. Although we are not finalizing the proposed transparency into kidney transplant organ offers provisions at proposed § 512.442(b), we continue to support increasing transparency for patients on the waiting list and will consider alternative pathways with the transplant community to fulfill this important need.

Comment: Numerous commenters voiced concerns about the transparency into kidney transplant organ offers requirements. Specifically, they worried that notifying patients about declined organ offers could undermine patient trust, evoke strong emotions, and negatively impact mental health. Commenters also expressed concern that patients and families may not fully grasp complex medical factors like organ quality and suitability, potentially leading to confusion over the clinical decisions made.

Response: We appreciate the commenters' feedback and agree that monthly notifications of declined organ offers may not be the right option for every patient. We believe this is an important topic to consider as we evaluate future opportunities for transparency requirements. At this time, we will not be finalizing the proposed transparency into kidney transplant organ offers provisions; however, we will take this feedback into consideration for future notice and comment rulemaking.

Comment: Several commenters mentioned that patient-centered and secure reporting is important stating that CMS should consider beneficiaries' preferences to ensure that the transparency requirements are practical for IOTA participants to implement and meaningful to kidney transplant patients and should ensure that data reported is meaningful. A commenter specified the information should be culturally and linguistically appropriate. Several commenters stated that information should be processed in a way that safeguards patients and their families, and authentication measures should be implemented to verify that patients' contact information. Commenters added that mechanisms for sharing information should be developed carefully and with input from the donation and transplant community. Some of these commenters also felt patients should be able to opt in and out of receiving notifications.

Response: We appreciate the commenters' feedback. We agree that organ offer notifications in addition to organ offer acceptance criteria need to be practical and consider linguistic and cultural modifications. Although we are not finalizing the proposed transparency into kidney transplant organ offers provisions, as mentioned in comment responses in this section, we will consider these important patient-centered provision details in future notice and comment rulemaking.

Comment: A commenter recommended that rather than report monthly on kidney transplant offers, CMS should require IOTA participants to report their quartile rank for their organ offer acceptance rate ratio to all wait-listed patients on a semiannual or annual basis.

Response: Thank you for your recommendation. As described in section III.C.5.d of this final rule, we are finalizing the inclusion of the organ offer acceptance rate ratio performance measure in the efficiency domain. Section 1115A(b)(4)(B) of the Act requires CMS to the public, and we plan to do so annually. This report would include the organ offer acceptance rate ratio results. Despite making organ offer acceptance rate ratio results available to patients, we believe that this does not negate the need for other transparency requirements as one data point focuses on kidney transplant hospital level data while the other focuses on patient level data. Although we are not finalizing the proposed transparency into kidney transplant organ offers provisions, as mentioned in comment responses in this section, this remains an important topic requiring ongoing discussion.

Comment: A couple of commenters recommended that organ offer declines be shared with both the patient and their referring nephrologist.

Response: We appreciate the commenters' feedback and agree that referring nephrologists are an important individual in the care continuum for patients with kidney disease. 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. After consideration of public comment, for the reasons set forth in this rule, we are not finalizing our proposed provision for transparency into kidney transplant organ offers at § 512.442(b).

We are, however, finalizing the provisions as proposed at § 512.442(c), with minor technical corrections. 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''. These changes were made in order to clarify the specific provisions regarding the review of transplant organ offer acceptance criteria, as described in section III.C.8(a)(2) of the preamble in this final rule. We will provide further sub-regulatory guidance on the specifics of how IOTA waitlist patients who are Medicare beneficiaries can decline reviewing their transplant organ offer acceptance criteria.

(3) Publication of IOTA Participant Results

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 part 512.140(a).

Consistent with these provisions, we proposed in section III. C.8.a(3) of the proposed rule, to publish results from all PYs of the IOTA Model. Specifically, for each PY, we intend to post performance across the achievement domain, efficiency domain, and quality domain for each IOTA participant. We would also identify each IOTA participant for the PY. The results would be published on the IOTA Model website. Given that we have proposed that the IOTA Model would include a process for IOTA participants to request a targeted review of the calculation of performance score which is calculated based on the various rates we intend to publish, CMS anticipates that it would publish these rates only after they have been finalized and CMS has resolved any targeted review requests timely received from IOTA participants under section II.E. of this final rule. We believed that the release of this information would inform the public about the cost and quality of care and about IOTA participants' performance in the IOTA Model. This would supplement, not replace, the annual evaluation reports that CMS is required to conduct and release to the public under section 1115A(b)(4) of the Act.

In section III.C.8.a(3) of the proposed rule, we considered requiring IOTA participants to publish their performance results on their own websites as well to increase transparency; however, we did not want to place additional reporting burden on IOTA participants, particularly because we proposed that CMS would publish the performance results, which should be adequate.

We sought comment on our intent to post this information to our website, as well as the information we intend to post and the manner and timing of the posting.

The following is a summary of comments received on our intent to publish this information to our website, as well as the information we intend to post and the manner and timing of the posting and our responses:

Comment: A commenter urged CMS to ensure that any data shared on the CMS website is easily understandable for the public.

Response: We thank the commenter for their feedback. We agree that it is important for patients to have information that is presented in a format that is easily reviewed and understood. We will review the results to be published and further consider how to best present information to both the public and kidney transplant hospitals in a meaningful manner, while abiding by the requirements of section 1115A(b)(4) of the Act.

Comment: A commenter stated that sharing results during the test phase should be limited to enrolled IOTA participants to avoid confusion and inequities.

Response: We thank the commenter for their recommendation and sharing their concerns, however, section 1115A(b)(4)(B) of the Act requires that model evaluation results be made available to the public. We believe it is important for patients to have model information available to them as they review IOTA participants. Additionally, access to these reports by all patients invites further research and evaluation by the transplant community to identify model requirements that should be applied to all kidney transplant hospitals and to identify areas of necessary changes in future iterations of the IOTA Model and transplant policy.

Comment: A commenter suggested that CMS should develop charts or other tools that track and communicate performance to IOTA participants in real-time. The commenter also suggested that performance-related information should be made available to providers in addition to IOTA participants so they can better identify areas for improvement and change behaviors as necessary before each performance year ends.

Response: We appreciate the commenter's feedback. We suggest referring to section III.C.7 of this final rule, on data sharing, for more detailed comment and will consider this request for timely performance reports as we develop implementation methodology for data collection and data reporting to IOTA participants.

Comment: A few commenters relayed their support for the publication of IOTA participant results. A commenter stated that they are eager to evaluate the model after its conclusion to determine whether the three domains were effective and whether the IOTA Model goals have been achieved, but also want to reevaluate further future improvements, encouraging CMS to publish annual interim reporting to assess the model's progress.

Response: We thank the commenters for their support and we reiterate the importance of transparency of performance results of IOTA participants to understand the pros and cons of the IOTA Model, what to modify in future iterations of the IOTA Model, and what components should be part of routine care for all kidney transplant hospitals in the future. Additionally, these performance results give patients, the transplant community and IOTA participants the opportunity to compare kidney transplant hospitals and identify where there is room for improvement year over year.

After consideration of public comments, for the reasons set forth in this rule, we are finalizing our proposals to publish results from all PYs of the IOTA Model, without modification, as outlined in section III.C.8.a(3) of this final rule. Specifically, 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. 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 interim performance results in future rulemaking. We direct readers to section III.C.7 of this final rule, for further details on data sharing.

b. Health Equity Data Reporting

(1) Demographic Data Reporting

As previously discussed in section III.B. of this final rule, and throughout this final rule, disparities exist

throughout the transplant process. These circumstances highlight the importance of data collection and analysis that includes race, ethnicity, language, disability, sexual orientation, gender identity, and sex characteristics or other demographics by health care facilities. Such data are necessary for integration of health equity in quality programs, because the data permits stratification by patient subpopulation.[307] [308] Stratified data can produce meaningful measures that can be used to expose health disparities, develop focused interventions to reduce them, and monitor performance to ensure interventions to improve care do not have unintended consequences for certain patients.[309] Furthermore, quality programs are carried out with well-known and widely used standardized procedures, including but not limited to, root cause analysis, plan-do-study-act (PDSA) cycles, health care failure mode effects analysis, and fish bone diagrams. These are common approaches in the health care industry to uncover the causes of problems, show the potential causes of a specific event, test a change that is being implemented, prevent failure by correcting a process proactively, and identify possible causes of a problem and sort ideas into useful categories, respectively.[310] [311] [312] [313] Adding a health equity prompt to these standardized procedures integrates a health equity lens within the quality structure and cues considerations of the patient subpopulations who receive care and services from a transplant hospital.[314]

To align with other Innovation Center efforts, we considered proposing that, beginning with the first PY and each PY thereafter, each IOTA participant would be required to collect and report to CMS demographic and SDOH data pursuant to 42 CFR part 403.1110(b) for the purposes of monitoring and evaluating the model. We considered proposing that, in conducting the collection required under this section, the IOTA participant would make a reasonable effort to collect demographic and social determinants of health data from all attributed patients but, in the case the IOTA participant attributed patient elects not to provide such data to the IOTA participant, the IOTA participant would indicate such election by the attributed patient in its report to CMS.

We decided not to propose the collection of demographic data as this data is already collected by OPOs and the SRTR, thereby making such a requirement for purposes of this model potentially duplicative and unnecessarily burdensome. We wish to minimize reporting burden on IOTA participants where possible to ensure sufficient time and effort is spent adjusting to the requirements of a mandatory model.

We solicited public comment on the decision not to propose the collection of this data and potential applications.

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

Comment: A few commenters agreed with CMS' decision not to propose the collection of demographic data as this data is already collected, thereby making such a requirement for purposes of this model potentially duplicative and unnecessarily burdensome.

Response: We thank commenters for their support in our decision to not include demographic data reporting in the IOTA Model.

After consideration of the public comments we received, we are not finalizing any requirements to include demographic data reporting in the IOTA Model.

(2) Health Related Social Needs (HRSN) Data Reporting

The Innovation Center is charged with testing innovations that improve quality and reduce the cost of health care. There is strong evidence that non-clinical drivers of health are the largest contributor to health outcomes and are associated with increased health care utilization and costs.[315] [316] These individual-level, adverse social conditions that negatively impact a person's health or healthcare are referred to as ''health-related social needs'' or HRSNs.[317] CMS aims to expand the collection, reporting, and analysis of standardized HRSNs data in its efforts to drive quality improvement, reduce health disparities, and better understand and address the unmet social needs of patients. Standardizing HRSN Screening and Referral as a practice can inform larger, community-wide efforts to ensure the availability of and access to community services that are responsive to the needs of Medicare beneficiaries.

HRSN screening is becoming increasingly common nationally, but implementation is not uniform across geography or health care setting. A literature review of national surveys measuring prevalence of social screening found that almost half of State Medicaid agencies have established managed care contracting requirements for HRSN screening in Medicaid.[318] It also found that health care payers and delivery organizations or both reported a screening prevalence of 55–77 percent, with ''the highest estimate reported among American Hospital Association member hospitals.'' [319] Despite screening proliferation and generally positive views toward screening among both patients and health care providers, implementation of screening and referral policies for beneficiaries of CMS programs with similar health—and even demographic—profiles may be inconsistent, potentially exacerbating

[307] IOM (Institute of Medicine). 2009. *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement* (p.287). The National Academies Press *https://www.ahrq.gov/sites/default/files/publications/files/iomracereport.pdf.*

[308] Sivashanker, K., & Gandhi, T.K. (2020). Advancing Safety and Equity Together. *New England Journal of Medicine, 382*(4), 301–303. *https://doi.org/10.1056/nejmp1911700.*

[309] Weinick, R.M., & Hasnain-Wynia, R. (2011). Quality Improvement Efforts Under Health Reform: How To Ensure That They Help Reduce Disparities—Not Increase Them. *Health Affairs, 30*(10), 1837–1843. *https://doi.org/10.1377/hlthaff.2011.0617.*

[310] American Society for Quality. (2019). *What is root cause analysis (RCA)? Asq.org. https://asq.org/quality-resources/root-cause-analysis.*

[311] Agency for Healthcare Research and Quality. (2020). *Plan-Do-Study-Act (PDSA) directions and examples. www.ahrq.gov. https://www.ahrq.gov/health-literacy/improve/precautions/tool2b.html.*

[312] *Failure Modes and Effects Analysis (FMEA) Tool | IHI—Institute for Healthcare Improvement.* (2017). *www.ihi.org. https://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx.*

[313] Kane, R. (2014). *How to Use the Fishbone Tool for Root Cause Analysis. https://www.cms.gov/medicare/provider-enrollment-and-certification/qapi/downloads/fishbonerevised.pdf.*

[314] Sivashanker, K., & Gandhi, T.K. (2020). Advancing Safety and Equity Together. *New England Journal of Medicine, 382*(4), 301–303. *https://doi.org/10.1056/nejmp1911700.*

[315] Booske, B.C., Athens, J.K., Kindig, D.A., Park, H., & Remington, P.L. (2010). *County Health Rankings* (Working Paper). *https://www.countyhealthrankings.org/sites/default/files/differentPerspectivesForAssigningWeightsToDeterminantsOfHealth.pdf.*

[316] *ROI Calculator for Partnerships to Address the Social Determinants of Health Review of Evidence for Health-Related Social Needs Interventions.* (2019). *https://www.commonwealthfund.org/sites/default/files/2019-07/COMBINED-ROI-EVIDENCE-REVIEW-7-1-19.pdf.*

[317] Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End- Stage Renal Disease Treatment Choices model NPRM (citing A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool) 87 FR 38554 (Jun. 28, 2022).

[318] De Marchis, E., Brown, E., Aceves, B., Loomba, V., Molina, M., Cartier, Y., Wing, H., Ma, L., & Gottlieb. (n.d.). *State of the Science of Screening in Healthcare Settings siren State of the Science on Social Screening in Healthcare Settings Summer 2022. https://sirenetwork.ucsf.edu/sites/default/files/2022-06/final%20SCREEN%20State-of-Science-Report%5B55%5D.pdf.*

[319] Ibid.

disparities in the comprehensiveness and quality of care.

One of the goals stated in the Innovation Center Strategy Refresh for advancing system transformation is to require all new models to collect and report demographic and SDOH data. Thus, in addition to the proposed health equity requirements in section III.C.8.b. of this final rule, we considered proposing a requirement that IOTA participants conduct HRSN screening for at least four core areas—food security, housing, transportation, and utilities. We recognize these areas as some of the most common barriers to kidney transplantation and the most pertinent for the IOTA participant patient population. However, given the need for a psychosocial evaluation prior to addition to the waitlist, we understand that such a requirement may be redundant given current clinical practices, we have refrained from making such a proposal.

We sought comment on whether we should include a requirement for IOTA participants to conduct HRSN screening and report HRSN data in a form and manner specified by CMS each PY for their attributed patients. We sought input on following the questions in this section, and comment on any aspect of the psychosocial evaluation of waitlisted patients and how this compares to HRSN screenings for the four domains—food security, housing, transportation, and utilities. Even if CMS were to adopt an HRSN screening and reporting requirement in the final rule, CMS might consider delaying the implementation of such a requirement.

- When evaluating a patient for potential addition to the kidney transplant waitlist, what questions are asked as part of the psychosocial evaluation?
- How might a psychosocial evaluation compare to an HRSN screening? What HRSNs are identified as part of a psychosocial evaluation?
- What data is collected from the psychosocial evaluation on HRSNs?
- If HRSNs are identified as part of the evaluation process, what, if any, steps are taken to assist the patient in addressing these needs and improving their transplant readiness?
- If HRSNs are identified of a patient already on the transplant waitlist, how might this affect their status on the transplant waitlist? Could a patient be removed from the transplant waitlist if HRSNs are identified that may impact transplant readiness?
- What, if any, follow-up is conducted with waitlist patients that have identified HRSNs?
- Are there any concerns with HRSN screening and data collection requirements?

We received 33 submissions on this RFI. We thank commenters for their comments. While we will not be responding to specific comments submitted in response to this RFI, we have shared all the comments received with the appropriate agencies and offices for consideration in subsequent rulemaking for the inclusion of demographic data reporting.

c. Health Equity Plans

To further align with other Innovation Center models and promote health equity across the transplant process, we proposed that, for PY 2 through PY 6, each IOTA participant must submit to CMS, in a form and manner and by the date(s) specified by CMS, a health equity plan. Given that this would be a mandatory model, we proposed that the health equity plan be voluntary in the first PY of the model to allow IOTA participants time to adjust to model requirements. We proposed that the health equity plan must:

- Identify target health disparities. We proposed to define ''target health disparities'' as health disparities experienced by one or more communities within the IOTA participant's population of attributed patients that the IOTA participant would aim to reduce.
- Identify the data sources used to inform the identification of target health disparities.
- Describe the health equity plan intervention. We proposed to define ''health equity plan intervention'' as the initiative(s) the IOTA participant would create and implement to reduce target health disparities.
- Include a resource gap analysis. We proposed to define ''resource gap analysis'' as the resources needed to implement the health equity plan interventions and identifies any gaps in the IOTA participant's current resources and the additional resources that would be needed.
- Include a health equity project plan. We proposed to define ''health equity project plan'' as the timeline for the IOTA participant to implement the IOTA participant's the health equity plan.
- Identify health equity plan performance measure(s). We proposed to define ''health equity performance plan measure(s)'' as one or more quantitative metrics that the IOTA participant would use to measure the reductions in target health disparities arising from the health equity plan interventions.
- Identify health equity goals and describes how the IOTA participant would use the health equity goals to monitor and evaluate progress in reducing targeted health disparities. We proposed to define ''health equity goals'' as targeted outcomes relative to the health equity plan performance measures for the first PY and all subsequent PYs.

In the proposed rule, we proposed that once an IOTA participant submits their health equity plan to CMS, CMS would use reasonable efforts to approve or reject the health equity plan within 60 business days (89 FR 43582). We proposed that if CMS approves the IOTA participant's health equity plan, the IOTA participant must engage in activities related to the execution of the IOTA participant's health equity plan, including implementing health equity plan interventions and monitoring and evaluating progress in reducing target health disparities. Discrimination on the basis of race, ethnicity, national origin, religion, or gender in activities related to the execution of the IOTA participant's health equity plan would be prohibited.

Should CMS determine that the IOTA participant's health equity plan does not satisfy the proposed requirements and is inconsistent with the applicable CMS Health Equity Plan guidance, does not provide sufficient evidence or documentation to demonstrate that the health equity plan is likely to accomplish the IOTA participant's intended health equity goals, or is likely to result in program integrity concerns or negatively impact beneficiaries' access to quality care, we proposed that CMS may reject the health equity plan or require amendment of the health equity plan at any time, including after its initial submission and approval (89 FR 43582).

We proposed that if CMS rejects the IOTA participant's health equity plan, in whole or in part, the IOTA participant must not, and must require its IOTA collaborators to not, conduct health equity activities identified in the health equity plan that have been rejected by CMS (89 FR 43582).

We proposed that in PY 3, and each subsequent PY, in a form and manner and by the date(s) specified by CMS, each IOTA participant would be required to submit to CMS an update on its progress in implementing its health equity plan (89 FR 43582). We stated that this update would be required to include all of the following:

- Updated outcomes data for the health equity plan performance measure(s).

- Updates to the resource gap analysis.
- Updates to the health equity project plan.

We proposed that if an IOTA participant fails to meet the requirements of the heath equity plan described in this section of the proposed rule, the IOTA participant would be subject to remedial action as specified in section III.C.16. of this final rule. Such remedial actions could include requesting a corrective action plan, recoupment of any upside risk payments; or termination from the model (89 FR 43582).

We solicited feedback on these proposals. We also solicited comment on the potential impact of creation of a health equity plan, whether such plans should be voluntary, and whether health equity plans should only be a requirement in later PYs of the IOTA Model.

The following is a summary of the comments received on our proposed health equity plan provisions, whether such plans should be voluntary, and whether health equity plans should be a requirement in later PYs of the IOTA Model and our responses:

Comment: Several commenters applauded CMS' proposed requirement to integrate health equity plans into the model framework. Commenters expressed support stating the health equity plans provide a context-specific system-level approach to addressing the social determinants of health and the health equity plan provision will encourage IOTA participants to identify health equity gaps and to develop and implement targeted strategies to address those gaps.

Response: We appreciate the commenters' support of the IOTA health equity plan. We acknowledge commenters' support for CMS' and the IOTA model's goal to promote health equity across the transplant process.

Comment: A few commenters suggested that CMS should not pursue the health equity plan provision. Several commenters supported the proposed requirements to delay the submission of the heath equity plans until performance year two, however, other commenters recommended CMS reconsider requiring each IOTA participant to submit to CMS an update on its progress in implementing its health equity plan (in PY 3, and each subsequent PY). Some commenters expressed the health equity plan requirement would be burdensome and inhibit IOTA participants resources and their ability to successfully implement and operationalize the model requirements. For example, commenters stated the health equity plans would be an unfair requirement and burdensome for transplant hospitals that have a larger low-income patient population and would penalize model participants' efforts to address health equity issues. Other commenters suggested that to reduce burden, CMS should provide clarity on the health equity plan criteria. For example, commenters stated CMS should consider providing IOTA participants examples of a comprehensive health equity plan that describes the health equity plan inclusion criteria, and clear and measurable endpoints on which CMS would deem suitable for approval.

Response: We thank the commenters for their feedback. However, we disagree with the suggestion to remove the health equity plan provision from the model. We believe health equity plans are vital to incentivize meaningful changes and promote health equity across the transplant process. However, we recognize that the IOTA health equity plan requirement may be burdensome for some model participants, and CMS solicited comment on whether such plans should be voluntary. With respect to comments received, we are modifying our proposal to allow health equity plans to be a voluntary provision for all performance years.

Comment: Several commenters recommended that CMS provide upfront investment funding to support the development and implementation of the IOTA participants' health equity plans. Several commenters stated the health equity plan requirements would be burdensome to model participants and would require significant resources and investments involving administrative, human and operational capital from model participants to be successful. In addition, some commenters stated that the health equity plan requirement fails to consider or address patients' barriers such as high out-of-pocket costs, or patients living in rural areas.

Other commenters expressed their support of the health equity plan policy but expressed concerns that the lack of upfront investments of resources and the design rigor would make the health equity plan requirements unlikely to yield meaningful results for patients. For example, these commenters suggested CMS should include upfront financial support to help empower participating hospitals to fully engage in the IOTA Model without compromising their financial stability or the quality of care they provide to their communities and patients. A commenter stated that tasking transplant hospitals to address patient's social risk factors and the social determinants of health via the health equity plan is beyond the purview or expertise of transplant hospitals. The commenter stated that the social determinants of health issues among transplant hospital patients are generally managed by social workers (and/or non-clinical staff) within the patients' communities, and therefore, supplemental funding would be needed to hire appropriate staff and support the resources needed to design and implement the IOTA health equity plan. Other commenters suggested CMS should consider issuing waivers to allow for broader financial assistance programs for underserved communities who may be facing additional barriers and social risk factors such as food insecurity, housing insecurity, inaccessible transportation and high childcare costs. A commenter suggested CMS should include additional incentives or supplemental funding for local healthcare providers and dialysis units to screen patients for social determinants of health metrics and link patients to community-based services.

Response: We appreciate the commenters' suggestions for CMS to include supplemental funding for the health equity plan provision. We believe it is important that IOTA participants receive the necessary support to successfully implement their health equity plan. We sought comment on the potential impact of creation of a health equity plan, and we will consider including health equity plan supplemental funding opportunities in future rulemaking.

Comment: Some commenters expressed concern that the health equity plan provision may promote discriminatory practices on the basis of race. Specifically, commenters stated the health equity plan requirement incentivizes model participants to prioritize certain group(s) over others in a discriminatory manner. A commenter suggested that the IOTA health equity plan ''target health disparities'' requirement should be defined in race-neutral terms, and CMS should prohibit IOTA participants' health equity plans from being implemented in a discriminatory manner.

Response: We acknowledge the commenters concerns. Our proposal states that ''discrimination on the basis of race, ethnicity, national origin, religion, or gender in activities related to the execution of the IOTA participant's health equity plan would be prohibited.'' We believe there are significant safeguards in place to assure health equity plans will not be designed or implemented in a discriminatory manner.

Comment: Some commenters recommended CMS implement the IOTA health equity plans through the CMS Hospital Inpatient Quality Reporting (IQR) Program. For example, commenters stated they do not agree that the IOTA model is an appropriate venue to promote health equity and the health equity plan provision would be better served within the IQR program given transplant hospitals already participant in IQR. Commenters suggested the IOTA health equity plan requirements would be duplicative, create additional administrative burden, and be confusing for hospitals given CMS has already introduced the Hospital Commitment to Health Equity via the IQR program. Other commenters suggested CMS should implement the model's health equity plans through The Joint Commission instead of an IOTA-specific plan. Another commenter recommended dialysis centers would be a more suited environment to implement health equity plans rather than via transplant hospitals.

Response: We disagree with implanting IOTA health equity plans within other CMS or hospital programs. The IOTA Model structure is designed to promote improvement activities across selected transplant hospitals, including the social determinants of health, and health equity. The IOTA health equity plans are designed specifically for the selected transplant hospital participants.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed provisions on health equity plans at § 512.444(a)(1–7) with slight modifications. Specifically, we are redesignating what was proposed at § 512.444 to be § 512.446. Additionally, we proposed at § 512.444(a) that the health equity plan be voluntary for IOTA participants for PY 1 and mandatory for PY 2 through PY 6. We are instead finalizing at § 512.446(a) that a health equity plan shall be voluntarily submitted by an IOTA participant for all performance years (PY 1 through PY 6) in a form and manner and by the date(s) specified by CMS. We are also finalizing that a health equity plan voluntarily submitted by an IOTA participant must include all elements as proposed at § 512.446(a)(1–7), without modification.

Additionally, we are finalizing as proposed without modification the definitions of target health disparities, health equity plan intervention, resource gap analysis, health equity project plan, health equity performance plan measure(s) and health equity goals at § 512.402. We also note that we are finalizing the proposed definition of health equity performance plan measure(s) with a slight modification to correct the defined term to read as follows: health equity plan performance measure(s). In the proposed rule at 89 FR 43582, we proposed to define health equity performance plan measure(s) as one or more quantitative metrics that the IOTA participant would use to measure the reductions in target health disparities arising from the health equity plan interventions. However, in the proposed rule at 89 FR 43582, we proposed that health equity plans must identify health equity plan performance measure(s). Additionally, in the proposed rule at 89 FR 43582, we proposed to define health equity goals as targeted outcomes relative to the health equity plan performance measures for the first PY and all subsequent PYs. As such, we are finalizing the definition of health equity plan performance measure(s) at § 512.402 as one or more quantitative metrics that the IOTA participant would uses to measure the reductions in target health disparities arising from the health equity plan interventions.

9. Overlap With Other Innovation Center Models, CMS Programs, and Federal Initiatives

a. Other Innovation Center Models and CMS Programs

We proposed that IOTA participants would be allowed to simultaneously participate in IOTA and other CMS programs and models. The IOTA Model would overlap with several other CMS programs and models and Departmental regulatory efforts, and we sought comment on our proposals to account for overlap.

KCC Model—The KCC Model is a voluntary Innovation Center model for nephrologists, dialysis facilities, transplant providers, and other providers and suppliers that are focused on beneficiaries with CKD and beneficiaries with ESRD. The KCC Model performance period began on January 1, 2022, and is scheduled to end December 31, 2026. As such, the KCC Model would run concurrently for 2 years with the IOTA Model, which would have a proposed start date of January 1, 2025. The KCC Model includes a payment incentive called the Kidney Transplant Bonus (KTB). KCC participants are eligible for up to $15,000 for every aligned beneficiary with CKD or ESRD who receives a kidney transplant, whether from a living or deceased donor, provided the transplant remains successful. Kidney Contracting Entities (KCEs) participating in the KCC Model are also required to include a transplant provider, defined as a transplant program that provides kidney transplants, a transplant hospital that provides kidney transplants, a transplant surgeon who provides kidney transplants, a transplant nephrologist, a transplant nephrology practice, an OPO, or another Medicare-enrolled provider or supplier that provides kidney transplant related covered services to Medicare beneficiaries.

Though transplant hospitals are one of the types of health care provider eligible to serve as a transplant provider, CMS has found relatively low participation by transplant hospitals in the KCC Model. Across the 100 KCEs participating in the model in 2023, there were only 10 kidney transplant hospitals participating in the model and serving as the transplant provider for the relevant KCE. In discussions with participants and with kidney transplant hospitals, CMS heard a few reasons for this relatively low rate of participation. CMS heard that it was difficult administratively for kidney transplant hospitals to participate as they are part of corporate entities that may have a larger organizational focus on broader shared savings efforts, rather than just for the kidney population.

We proposed that any providers or suppliers participating in the KCC Model that meet the proposed IOTA participant eligibility requirements would still be required to participate in the IOTA Model. We believed that granting an exemption to the IOTA Model for these providers or suppliers could disrupt the patterns of care being tested in the KCC Model. We also believed that a prohibition on dual participation could prevent enough KCEs from having a transplant provider and meeting model requirements, which could undermine participation in the KCC model.

We considered proposing that any transplant hospitals participating in the IOTA Model would not be able to participate in the KCC Model and be able to receive any portion of a Kidney Transplant Bonus payment. However, we did not believe that this was necessary given that there are currently only 10 transplant hospitals participating in the KCC Model, meaning that dual participation should not substantially affect the evaluation of either model. We also considered proposing that any kidney transplant for an aligned beneficiary that results in a Kidney Transplant Bonus being paid out in the KCC Model would not be counted for calculating an upside risk payment or downside risk payment in the IOTA Model. We decided not to propose this policy because of potential disruption to

the KCC Model, which would be in its fourth performance year when the proposed IOTA Model would likely begin in 2025. Additionally, the Kidney Transplant Bonus payment in the KCC Model serves multiple functions within that model, as it also incentivizes post-transplant care for up to three years post-transplant.

We believed that it is important to test both the IOTA Model and the KCC Model, to test the effectiveness of payment incentives for kidney transplants at different points of the care coordination process. The IOTA Model would test the effect of upside and downside risk payments for kidney transplant hospitals, while the KCC Model tests how nephrologists and other providers and suppliers can support transplantation in the overall care coordination process. Upside risk payment and downside risk payment from the IOTA Model would not be counted as expenditures for purposes of the KCC Model, as they would not be adjustments to claims for individual beneficiaries, but would be paid out in a lump sum based on aggregate performance directly tied to individual beneficiary level claims. Additionally, we do not want to potentially hurt KCC participants that have beneficiaries who could benefit from the KCC participant's potential high performance in the IOTA Model.

Both the KCC Model and the IOTA Model would include explicit incentives for participants when aligned beneficiaries receive kidney transplants; and a transplant hospital participating in both models would be eligible to receive a portion of a Kidney Transplant Bonus from a KCE under the KCC Model and an upside risk payment or downside risk payment under the IOTA Model. Kidney transplants represent the most desired and cost-effective treatment for most beneficiaries with ESRD, but providers and suppliers may currently have insufficient financial incentives to assist beneficiaries through the transplant process because dialysis generally results in higher reimbursement over a more extended period of time than a transplant. As a result, CMS believed it would be appropriate to allow a transplant hospital to receive both an upside risk payment or downside risk payment from the IOTA Model and portion of a Kidney Transplant Bonus from the KCC Model and the IOTA Model simultaneously to assess their effects on the transplant rate.

ETC Model—The ETC Model is a mandatory Innovation Center model that includes as participants certain clinicians who manage dialysis patients (referred to as Managing Clinicians) and ESRD facilities and provides incentives for increasing rates of home dialysis, transplant waitlisting, and living donor transplantation. The ETC Model began on January 1, 2021, and the model performance period is scheduled to end December 31, 2025, and it would have one year of overlap with the proposed model performance period of the IOTA Model beginning January 1, 2025. The ETC Model includes an upward or downward payment adjustment called the Performance Payment Adjustment (PPA) that is calculated in part based on the rates of transplant waitlisting and living donor transplants for the population of beneficiaries aligned to a participating Managing Clinician or ESRD facility.

We believed that the goals of the ETC Model and the goals of the proposed IOTA Model are aligned. As CMS described in the 2020 rule finalizing the ETC Model (85 FR 61114), ''[t]he ETC Model [is] a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants.'' We believe that the IOTA Model would then test a corresponding incentive on the transplant hospital side to further assist beneficiaries in moving through the transplant process to get a transplant. CMS believed it is appropriate to test both models as the ETC Model does not include direct incentives for transplant hospitals and we believe that transplant hospitals play a very important role in the transplant process.

We note for the ETC Model, participants are selected based on their location in a Selected Geographic Area, which are randomly selected Hospital Referral Regions (HRR), stratified by census region, representing approximately one third of the country, as well as HRRs predominately comprised of ZIP codes in Maryland. This is a different randomization strategy than is being proposed for the IOTA Model. It is our intent to look at the effects of each model and its randomization strategy on the transplant rate as part of our model evaluation, which is discussed in section III.C.12 of this final rule.

Additionally, we note that the ETC Model includes the ETC Learning Collaborative as part of its model test. This is further discussed in section III.C.13. of this final rule, where we sought feedback about the experience of kidney transplant hospitals, OPOs, ETC Participants, and other interested parties engaged in the ETC Learning Collaborative, as we consider how to best promote shared learning in the IOTA Model.

Other Medicare Alternative Payment Models (APMs)—For the Medicare Shared Savings Program (the Shared Savings Program) and the ACO Realizing Equity, Access, and Community Health (ACO REACH) Model, which focus on total cost of care, payment adjustments made under the IOTA Model would not be counted as program expenditures. The Medicare Shared Savings Program regulations address payments under a model, demonstration, or other time-limited program when defining program expenditures. Specifically, when calculating Shared Savings and Shared Losses for an ACO in the Shared Savings Program, CMS considers only ''individually beneficiary identifiable final payments made under a demonstration, pilot, or time limited program'' to be a part of the ACO's Medicare Parts A and B fee-for-service expenditures (see, for example, 42 CFR 425.605(a)(5)(ii)). Similarly, in the ACO REACH Model, an ACO's performance year expenditure is defined to include the total payment that has been made by Medicare fee-for-service for services furnished to REACH Beneficiaries (see ACO REACH Model First Amended and Restated Participation Agreement (Dec. 1, 2023)). Payments under the IOTA Model are not directly tied to any specific beneficiary. Instead, they are made on a lump sum basis based on aggregate performance across transplant patients seen by the center during the performance year. IOTA Model payments, therefore, would not be considered by the Shared Savings Program as an amount included in Part A or B fee-for-service expenditures or by the ACO REACH Model as an amount included in payment for REACH Beneficiaries' Medicare fee-for-service services.

Hospital VBP Program—CMS adjusts payments to hospitals under the Inpatient Prospective Payment System (IPPS) based on their performance under the Hospital VBP Program. However, the Hospital VBP Program does not currently include any measures related to transplant services. In addition, transplant services are only offered by a subset of hospitals. Given the different focuses between the Hospital VBP Program and the IOTA Model, we are not proposing any changes to the Hospital VBP Program and believe it is appropriate to test the IOTA Model alongside the existing Hospital VBP Program.

b. Overlap With Departmental Regulatory Efforts

December 2020 OPO Conditions for Coverage—In December 2020, CMS

issued a final rule titled ''Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final Rule'' (85 FR 77898). The final rule revised the OPO CfCs and was intended to increase donation rates and organ transplantation rates by replacing the previous outcome measures. In general, the new outcome measures improve on the prior measures by using objective, transparent, and reliable data, rather than OPO self-reported data, to establish the donor potential in the OPO's DSA. The rule also permits CMS to begin decertifying underperforming OPOs beginning in 2026.

We believed that the proposed IOTA Model supports the policies set out in that final rule. We noted that we have received feedback from OPOs and other interested parties that OPOs are required to procure more organs, while there is not a corresponding incentive on the transplant hospital side to transplant more organs into beneficiaries. We also noted that the number of discarded organs has risen from 21 percent to 25 percent from 2018 to 2022.[320] Though there have been other changes during that time, including the updated organ allocation system and the effects of the COVID–19 pandemic, this rise in discarded organs is highly concerning, and we believed that the IOTA Model can help to mitigate this troubling rise by giving transplant hospitals an incentive to accept more offers that they may not have accepted without that incentive.

In September 2019, CMS finalized a rule titled ''Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51732). This rule was in part motivated by a commitment across CMS and HHS to ''the vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework.''

One of the major provisions finalized in this rule was the removal of data submission, clinical experience, and outcomes requirements for Medicare re-approval that were previously required of transplant hospitals participating in the Medicare program. As described in the rule, CMS had put in place additional CoPs in the March 2007 final rule (72 FR 15198) in an effort to increase the quality of care by specifying minimal health and safety standards for transplant hospitals. In addition, outcome metrics (1 year graft and patient survival) were included in the regulation and mirrored the OPTN outcomes metrics as calculated by the SRTR.

CMS removed the outcomes requirements for a few key reasons. First, the concern was that transplant centers were also subject to OPTN policies, so parallel regulation on the CMS side was duplicative. Additionally, the concern was that ''increased emphasis on organ and patient survival rates, as key metrics of transplant performance, created incentives for transplant programs to select organs most likely to survive after transplant without rejection, and to select recipients most likely to survive after the transplant.'' This focus had the effect of creating ''performance standards that focused only on organ and patient survival rates for those who received a transplant, not on survival rates of patients awaiting transplant.'' [321]

In December 2021, CMS published an RFI titled ''Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities'' (86 FR 68594).[322] In this RFI, CMS asked questions about the overall transplant ecosystem, with goal of helping ''to inform potential changes that would create system-wide improvements, which would further lead to improved organ donation, organ transplantation, quality of care in dialysis facilities, and improved access to dialysis services.''

We noted that we were seeking ways to harmonize policies across the primary HHS agencies (CMS, HRSA, and the Food and Drug Administration (FDA)) that are involved in regulating stakeholders in the transplant ecosystem so that our requirements are not duplicative, conflicting, or overly burdensome. We asked if there any current requirements for transplant programs, ESRD facilities, or OPOs that are unnecessarily duplicative of, or in conflict with, OPTN policies or policies that are covered by other government agencies. We also asked about the impacts of these duplicative requirements on organ utilization and transplant program/ESRD facility/OPO quality and efficiency (86 FR 68596).

Given the concerns described in these past efforts, the OPTN has been in part responsive to concerns from interested parties about their metrics and effects and has expanded which metrics they are evaluating transplant centers for their performance. In December 2021, the OPTN approved four new risk-adjusted metrics to be used to monitor transplant program performance, including 90-day graft survival hazard ratio, 1-year conditional graft survival hazard ratio, pre-transplant mortality rate ratio, and offer acceptance ratio.[323] This added two new metrics for areas beyond simply looking at transplant survival, and looked at a more holistic view of patient care for beneficiaries on the transplant list. There is a critical role for both the Department and the OPTN with regard to the transplant ecosystem. The final rule governing the operation of the OPTN from 1996 (63 FR 16296) stated the following:

The Department believes that the transplantation network must be operated by professionals in the transplant community, and that both allocation and other policies of the OPTN should be developed by transplant professionals, in an open environment that includes the public, particularly transplant patients and donor families. It is not the desire or intention of the Department to interfere in the practice of medicine. This rule does not alter the role of the OPTN to use its judgment regarding appropriate medical criteria for organ allocation nor is it intended to circumscribe the discretion afforded to doctors who must make the difficult judgments that affect individual patients. At the same time, the Department has an important and constructive role to play, particularly on behalf of patients. Human organs that are given to save lives are a public resource and a public trust.

We believed that the proposed IOTA Model recognizes the goals of the Department on behalf of the public and the medical judgment exhibited by the OPTN. We believed that constructing

[320] Sumit Mohan, Miko Yu, Kristen L. King, S. Ali Husain, Increasing Discards as an Unintended Consequence of Recent Changes in United States Kidney Allocation Policy, Kidney International Reports, Volume 8, Issue 5, 2023, Pages 1109–1111, ISSN 2468–0249, *https://doi.org/10.1016/j.ekir.2023.02.1081.*

[321] *https://www.federalregister.gov/d/2019-20736/p-87.*

[322] Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities. *https://www.federalregister.gov/documents/2021/12/03/2021-26146/request-for-information-health-and-safety-requirements-for-transplant-programs-organ-procurement.*

[323] *OPTN Board adopts new transplant program performance metrics—OPTN.* (2021, December 16). Optn.*transplant.hrsa.gov.* Retrieved May 30, 2023, from *https://optn.transplant.hrsa.gov/news/optn-board-adopts-new-transplant-program-performance-metrics/.*

this as a model test would enable the Department to test out a different approach to incentivize certain behavior for transplant centers, while also acknowledging the role of the OPTN and transplant professionals in this area.

We noted the concern put forward by kidney transplant hospitals that they would not be able to increase their number of transplants without potentially affecting their performance 90 day and 1-year graft survival rate metrics used by the MPSC. However, we believed that there are several different ways that IOTA participants would ultimately be able to succeed under the IOTA Model and OPTN policies:

- The MPSC standard represents a standard far below the national average of performance that should be able to be met by member transplant centers. The MPSC describes this as meaning that to be identified for outcomes review in a document describing their Performance Reviews,[324] ''[t]he adult criteria is based on the likelihood that the program's performance was at least 75 percent worse than an average program, accounting for differences in the types of recipients and donor organs transplanted. The pediatric criterion is based on the likelihood that the program's performance was at least 60 percent worse than an average program, accounting for differences in the types of recipients and donor organs transplanted. Even if a program meets one or both of the criteria for graft survival, the MPSC may not send the program an inquiry based on various situations, such as recent release from review for outcomes or program membership status.'' This represents a minimum standard of care and only a small percentage were flagged for not meeting those standards.
- The IOTA Model incentivizes investment in both living and deceased donor transplants. Living donor transplantation has rates that have been relatively flat for 20 years and has recipients of those organs with better post-transplant outcomes.
- MPSC outcomes metrics are risk adjusted based on organ quality and can account for the use of organs that are currently being discarded.
- Many organs currently being discarded are quality organs. Though the median KDRI of discarded kidneys was higher for discarded kidneys than transplanted kidneys, there is a large overlap in the quality of discarded and transplanted kidneys.[325]
- Per 42 CFR 121.10(c)(1), the reviews conducted by the OPTN result in an advisory opinion to the Secretary of a recommended course of action. The Secretary then has the option under 42 CFR 121.10(c)(2) of requesting additional information, declining to accept the recommendation, accepting the recommendation, or taking such other action as the Secretary deems necessary. Given the enforcement discretion given to the Secretary, the Secretary may take into account performance on the metrics evaluated in the IOTA Model as part of a holistic evaluation of transplant hospital performance.

Additionally, CMS also considered, but did not propose, a limited waiver of section 1138(a)(1)(B) of the Act as part of the IOTA Model, which requires that a hospital be a member and abide by the rules and requirements of the OPTN. We considered retaining transplant hospitals' membership obligations to the OPTN with the exception of their required responsiveness to MPSC transplant hospital performance reviews and the potential for adverse actions that may risk a transplant hospital's operations and reimbursement by Federal health insurance programs. However, we do not believe that this waiver is necessary for testing the model, and that a transplant hospital can perform on both the metrics put forward by the MPSC and demonstrate successful performance in the IOTA Model.

We invited public comments on our proposals to account for overlaps with other CMS programs and models.

The following is a summary of the comments received on our proposals to account for overlaps with other CMS programs and models and our responses:

Comment: We received multiple comments about the OPTN Modernization and concerns that the OPTN Modernization process is happening right now, as the IOTA Model is being implemented, which would potentially be too disruptive to the transplant system. We also received comments concerned about the solicitation for a new OPTN contractor and concerns that any potential transition that could happen from a new contract could lead to disruption that could impact ability to perform in the IOTA Model.

Response: We disagree with the commenters as we believe that the OPTN Modernization process will improve the system overall and includes a series of improvements in technology, governance, and organ tracking that will benefit IOTA participants as they participate in this model. At a high level, the IOTA Model was proposed and developed in coordination with CMS and HRSA in an effort to create a series of coordinated initiatives across the transplant ecosystem, using a variety of different levers to improve performance and equity in the United States transplant system. Through the OTAG, CMS and HRSA have collaborated and produced the IOTA Model, the OPTN Modernization Process, and further efforts to come including around the HIV Organ Policy Equity Act in an effort to increase accountability in the transplant system and improve it for patients.

Additionally, HRSA and the OPTN are committed that the Modernization Process will not disrupt existing procurement and allocation practices. HHS also believes that this modernization process will improve accountability and performance for the OPTN and accelerate progress in technology, data transparency and analytics, governance, operations, and quality improvement and innovation. Some key steps that have already been taken include in August 2024 separating the OPTN Board of Directors from the OPTN contractor so it may better serve the interests of patients and their families, which HHS believes will strengthen governance and prevent conflicts of interest within the Network. Other major steps include issuing a Request for Proposals for a multi-vendor contract solicitation for critical OPTN functions and a transition to an upgraded IT system that leverages industry-leading standards. The net result of these efforts will be a more functional and accountable system that will better be able to get and share data than in the status quo. We also believe that the delayed start date for model accountability to July 1, 2025, will enable the OPTN Modernization to progress further and allow for the awarding of these contracts and onboarding of new contractors before accountability begins. We also note that the randomized design of the model means that major national changes, like this OPTN Modernization effort, will apply equally to both the selected IOTA DSAs and the DSAs that are not selected and are in the comparison group, meaning that CMS will still be able to fully evaluate the impacts of the interventions in the IOTA Model.

Comment: We received multiple comments about the OPTN's

[324] *https://optn.transplant.hrsa.gov/media/5j5dov5s/what_to_expect_performance_reviews.pdf.*

[325] Mohan, S., Chiles, M.C., Patzer, R.E., Pastan, S.O., Husain, S.A., Carpenter, D.J., Dube, G.K., Crew, R.J., Ratner, L.E., & Cohen, D.J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International, 94*(1), 187–198. *https://doi.org/10.1016/j.kint.2018.02.016.*

Expeditious Task Force, with some concerns about the implications of overlapping initiatives both designed to increase number of transplants. A commenter specifically pointed out that a part of the Expeditious effort includes a proposed allocation variance to allow for the study of out-of-sequence allocation.

Response: We appreciate the comments and believe that overall, there is a great deal of synergy between the efforts being promoted as part of the Expeditious Task Force and the IOTA Model, starting with their initial aim of greatly increasing the number of transplants completed across the country. The Expeditious efforts include many different components, many of which will help selected IOTA participants perform better in the model. This includes efforts like analyzing patterns of non-use of kidneys, conducting data analysis to improve organ offer filters, and working on how to best secure commitments from hospital leadership to secure investment for the IOTA participant to be able to build up infrastructure to support a growth in kidney transplants. We believe that these efforts are incredibly helpful and will support improved performance in the achievement and efficiency domains in the IOTA Model.

We saw multiple comments about out-of-sequence allocation and the proposed limited trials being proposed by the Expeditious Task Force that are designed to test a proposed variance to the allocation methodology for certain OPOs. We note that these proposed trials are meant to last for only a few months and are meant to be limited in scope and do not believe that they would impact the ability to evaluate the IOTA Model. We also note that we described in the monitoring section of this rule that we plan to monitor out-of-sequence allocation in the context of the IOTA Model to see if that is a strategy used by IOTA participants to utilize more kidneys.

Comment: We received a comment saying that this model is being proposed to be implemented amidst too many other initiatives, including the proposed new OPTN data collection initiative.

Response: HHS believes that collecting the proposed data from OPOs and kidney transplant hospitals will be beneficial for patients, improve the overall transplant process, and help IOTA participants succeed in the IOTA Model. The transplant hospital forms will help to track sources of waitlist referral, the results of referrals, and the results of transplant evaluations to see who makes it onto the transplant waiting list. We believe that this data driven approach will help transplant hospitals better understand their sources of referral and potential areas of improvement in the waitlisting process that may allow for better waitlist management. The organ procurement forms will require OPOs to track how effective they are at responding to referrals from donor hospitals and how effective they are at procuring organs from potential donor candidates. We believe that this data driven approach will help OPOs with quality improvement to understand their success at different stages in the procurement process and will therefore help to increase the supply of organs for IOTA participants.

At the same time, HHS understands this potential criticism and will work to coordinate once the waitlist referral and evaluation forms are established, recognizing that it would be the same staff at transplant hospitals who would be likely to fill these out as those who would be working to increase the number of transplants under the IOTA Model. We also note that the proposed forms for transplant hospitals and OPOs will undergo a thorough public review process that began via **Federal Register** Notice on November 4, 2024.[326]

Comment: We received multiple comments about the metrics used by the MPSC, some pointing out the duplicative nature with the metrics that are a part of the IOTA Model and some worried that their performance on MPSC metrics may be hurt by their performance under the IOTA Model.

Response: As discussed previously in this section, we anticipated this concern and believe that there are several different ways that IOTA participants would ultimately be able to succeed under the IOTA Model and OPTN policies. Given the relatively low bar for the different metrics for the MPSC, the risk adjusted nature of their metrics, and the potential for increasing transplants with the quality organs that are currently going unused and the opportunity to increase living donation rates, we see many ways that participants will be able to be successful under both sets of metrics. Additionally, we constructed the IOTA Model in the context of the regulatory efforts through the OPTN and the CMS Transplant Center CfCs, recognizing that CMS is incentivizing more transplants for patients, but that we want to make sure they are done in a way that still ensures an appropriate level of patient safety.

Comment: We received a comment about the potential that OPTN will move to continuous allocation for kidneys, which could disrupt their operations.

Response: HHS recognizes that the OPTN is considering further adjustments to the organ allocation system. We believe that the randomly selection methodology in the IOTA Model will help to account for any changes to the allocation system, given the national focus of any of these changes. We also believe that the focus on organ offer acceptance rate in the model will encourage participating kidney transplant hospitals to carefully consider their organ offer filters, which will help to limit potential disruption to transplant operations.

We also received comments about the potential overlap between initiatives and regulations elsewhere within CMS and the IOTA Model.

Comment: We received multiple comments worried about implementation of the 2020 update to the OPO CfCs and their potential impact on OPO decertification, with worries about the potential effects of new OPOs coming in on organ allocation. We also received comments about the OPO CfC methodology that were out of scope.

Response: We recognize that implementation of accountability in the IOTA Model will intersect with the recertification period for OPOs in 2026. However, we believe that though there is a hypothetical potential for some disruption as a new OPO takes over a DSA, we believe that the interaction between the IOTA Model and the updated CfCs will ultimately be positive for both OPOs and transplant hospitals and will better allow both to perform better on their respective metrics. Since the updated CfCs were finalized in 2020, OPOs have been procuring more organs and have complained that there was not a corresponding incentive on the transplant hospital side to use more of the organs that are procured. Additionally, the number of organ offers and turndowns has grown since the updated CfCs and allocation system were finalized. We believe that the incentives in the IOTA Model will help to better ensure more judicious use of organ offer filters to better reflect potential for utilization, which will make it easier for OPOs to place the organs that they procure. CMS also commits to recognizing the potential for disruption with the decertification of

[326] U.S. Department of Health and Human Services. (2024, November 4). *Agency information collection activities; proposed collection; public comment request* [Docket No. HHS–2024–25522]. **Federal Register**. *https://www.federalregister.gov/documents/2024/11/04/2024-25522/agency-information-collection-activities-proposed-collection-public-comment-request-information.*

any OPO and will work to make this process as smooth as possible.

Comment: We received a comment asking CMS to prioritize waiver requests from hospitals seeking to work with a different OPO before taking action on creating a new transplant model.

Response: We appreciate this commenters suggestion and the importance of this issue; however, this comment is beyond the scope of this rule.

Comment: We received a comment from a hospital pointing out that they are already subject to the CMS Survey and Certification process, making the IOTA Model unnecessary.

Response: As discussed previously, in 2019, CMS removed any outcomes requirements from its Survey and Certification requirements. The IOTA Model focuses on increasing numbers of transplants and improving organ offer acceptance rate, neither of which were addressed in the previous version of the Survey and Certification requirements and includes financial incentives for performance that are not included in the CMS Survey and Certification process. We believe that this model test can complement existing Survey and Certification requirements as those will help to ensure a baseline level of patient care in the transplant process, while still enabling CMS to test out a new method to pay for care, without compromising care for patients.

Comment: We received some concern about the potential implications on the IOTA Model if CMS implements some previously proposed changes to the way that organ acquisition costs are calculated.

Response: In the FY 2022 IPPS Final Rule (CMS 1752–FC3), We decided not to finalize a proposed change to the way that Medicare's share of organ acquisition costs are calculated for centers. Based on the consideration of concerns received from commenters, CMS decided not to finalize the proposed policy with respect to counting organs at this time, but stated that we may consider it in future rulemaking.

We also received comments from the public about interaction with multiple efforts at the Innovation Center.

Comment: We received a comment from a dialysis company pointing out the potential for cooperation between selected IOTA transplant hospitals and participants in the existing ETC and KCC Models.

Response: We appreciate the comment, as these models were designed to fit together. Participating entities in the KCC Model have the opportunity to partner with selected IOTA participants and to even add them to their participant lists for an upcoming performance year. CMS encourages greater collaboration throughout the entire spectrum of transplant care and believes that alignment for patients from the first detection of CKD, through the need for dialysis, and all the way through the delivery of a transplant results in the best outcomes for most beneficiaries.

Comment: We received a comment from a hospital association urging that transplant hospitals participating in any Innovation Center Advanced APM model be able to opt out of the proposed IOTA Model.

Response: We disagree with the comment as CMS decided to make the model mandatory for reasons discussed previously in the relevant section. We recognize that many kidney transplant hospitals have made decisions to be involved in many other different value-based purchasing programs like the Shared Savings Program or another Innovation Center Model and allowing those involved in those other models to opt out could hurt the ability to evaluate the IOTA Model. We also recognize that none of these models, outside of the KCC Model which has seen a relatively low level of participation from kidney transplant hospitals, are particularly focused on transplantation, which we believe helps to show the need for a transplant-focused value-based care model.

Comment: We received a comment from one hospital expressing concern about being opted into both the IOTA Model and the TEAM Model, recently finalized by the Innovation Center, and were concerned about their ability to conduct change management at their hospital if they are selected into both models.

Response: The TEAM Model was finalized in the 2025 IPPS Rule in July 2024 (CMS–1808–F). We recognize the potential complications as CMS and particularly the Innovation Center tests multiple models at the same time. However, we believe that this model has very different goals than the TEAM Model, which is focused on surgical bundles for five procedures and post-acute care spending, rather than the transplant process. We also note that both models include a period of time before implementation, creating an opportunity for hospitals that are required to participate in both models' time to enact necessary changes in practice.

After consideration of the public comments we received, we are finalizing the overlaps policy in the model as proposed. The Innovation Center will continue to monitor developments in the transplant ecosystem to see if changes are needed to the model for unintended consequences. The Innovation Center is committed to continuing to work and coordinate with other components of CMS and HRSA as they continue to implement the updated OPO CfCs and the OPTN Modernization process in order to see if any actions do end up affecting the ability of selected IOTA transplant hospitals to perform in the model. These coordination efforts through the Organ Transplant Affinity Group are part of a larger HHS effort to ensure policy coordination and ensure input across HHS as we consider and implement reforms to the transplant system.

10. Beneficiary Protections

a. Beneficiary Notifications

At § 512.450 of the proposed rule, we proposed to require IOTA participants to provide notice to attributed patients that the IOTA participant is participating in the IOTA Model. We believed it would be important for IOTA participants to provide attributed patients with a standardized, CMS-developed, beneficiary notice to limit the potential for fraud and abuse, including patient steering. We intended to provide a notification template that IOTA participants would be required to use. This template would, at minimum, indicate content that the IOTA participant would not be permitted to change and would indicate where the IOTA participant could insert its own content. It would also include information regarding the attributed patient's ability to opt-out of data sharing with IOTA participants and how they may opt out if they choose to do so (89 FR 43518).

At § 512.450 of the proposed rule, we proposed requiring IOTA participants to display a notice containing these rights and protections prominently at each office or facility location where an attributed patient may receive treatment, in a clear manner on its public facing website, and to each attributed patient in a paper format. This would increase the probability that the attributed patients would receive and take note of this information.

We sought comment on the proposed requirements for beneficiary notifications.

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

Comment: Several commenters expressed support for requiring hospitals and providers to notify

patients about their participation in the IOTA Model.

Response: We thank the commenters for their support.

Comment: A commenter expressed concern that CMS should provide more information about the required notice of attribution, including expectations for hospitals and patients.

Response: We thank the commenter for its feedback. We will provide a template for the beneficiary notification that will have additional information concerning the notice of attribution. We will take the commenter's feedback into consideration as we draft the template.

Comment: Several commenters suggested that the beneficiary notifications should require an IOTA participant to notify patients of participation in IOTA in multiple languages and that CMS limit the requirement for beneficiary notifications to be provided only upon patient request and only at the main transplant hospital.

Response: We thank the commenters for their feedback. Although the IOTA Model does not require IOTA participants to provide beneficiary notifications in multiple languages, other federal laws and regulations that apply to language services will still apply to IOTA participants. Accordingly, we decline to include such requirements in the IOTA Model regulations at this time.

We also disagree with the suggestion that the notice only be required upon patient request. Many patients may not be aware of their rights and not know that such a request should be made. Additionally, we disagree with the suggestion that the notice only be required at the main location of the IOTA participant. It is possible that a beneficiary would not be seen at the main location of the IOTA participant and therefore not be properly informed.

After consideration of the public comments received, for the reasons set forth in this rule, we are finalizing our proposed provision to require IOTA participants to provide notice to attributed patients that the IOTA participant is participating in the IOTA Model, including the requirement to display a notice containing these rights and protections prominently at each office or facility location, at § 512.450, with minor technical corrections to update the spacing in the regulation and provide clarification, including the removal of duplicative text, at § 512.450(a)(3)(ii).

b. Availability of Services and Beneficiary Freedom of Choice

In section II.B of the proposed rule, we proposed the Standard Provisions for Innovation Center Models relating to availability of services and beneficiary freedom of choice would apply to the IOTA Model. These provisions were originally finalized as general provisions in the Code of Federal Regulations (42 CFR part 512 subpart A) that applied to specific Innovation Center models, but are finalized separately in section II.B of this final rule for expansion to all mandatory Innovation Center Models with performance periods that begin on or after January 1, 2025. Consistent with this final rule, IOTA participants will need to preserve beneficiary freedom of choice and continue to make medically necessary covered services available to beneficiaries to the extent required by applicable law.

We received no comments on these proposals and therefore are finalizing these proposals without modification.

11. Financial Arrangements and Attributed Patient Engagement Incentives

a. Background

We believe it is necessary to provide IOTA participants with flexibilities that could support their performance in the IOTA Model and allow for greater support for the needs of attributed patients. These flexibilities are outlined in this section and include the ability to engage in financial arrangements to share IOTA upside risk payments and responsibility for paying Medicare for IOTA downside risk payments with providers and suppliers making contributions to the IOTA participants' performance against model metrics, and the availability of the provision of attributed patient engagement incentives. Such flexibilities would allow IOTA participants to share all or some of the payments they may be eligible to receive from CMS and to share the responsibility for the funds needed to pay CMS providers and suppliers engaged in caring for attributed patients, if those providers and suppliers have a role in the IOTA participant's spending or quality performance. Additionally, we believe that IOTA participants caring for attributed patients may want to offer attributed patient engagement incentives to encourage adherence to recommended treatment and active patient engagement in recovery. These incentives may help an IOTA participant reach their quality and efficiency goals for the model, while also benefitting beneficiaries' health and the Medicare Trust Fund if the IOTA participant improves the quality and efficiency of care that results in the Medicare beneficiary's reductions in hospital readmissions, complications, days in acute care, and mortality, while recovery continues uninterrupted or accelerates.

b. Overview of IOTA Model Financial Arrangements

We believe that IOTA participants may wish to enter into financial arrangements with providers and suppliers caring for attributed patients to share model upside risk payments or downside risk payments, to align the financial incentives of those providers and suppliers with the IOTA Model goals of increasing the number of kidney transplants furnished to attributed patients to lower costs and to improve their quality of life. To do so, we expect that IOTA participants would identify key providers and suppliers caring for attributed patients in their communities and DSAs. The IOTA participants could establish partnerships with these providers and suppliers to promote accountability for the quality, cost, and overall care for attributed patients, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigning care processes for high quality and efficient service delivery; and carrying out other obligations or duties under the IOTA Model. These providers and suppliers may invest substantial time and other resources in these activities, yet they would neither be the direct recipients of any model upside risk payments from Medicare, nor directly responsible for paying to CMS any downside risk payments incurred. Therefore, we believe it is possible that an IOTA participant that may receive an upside risk payment from Medicare or may need to pay a downside risk payment to Medicare may want to enter into financial arrangements with other providers or suppliers to share these performance adjustments with the IOTA participant.

We require that all financial relationships established between IOTA participants and providers or suppliers for purposes of the IOTA Model would only be those permitted under applicable law and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements. As discussed in section III.C.3 of this final rule, CMS determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) is available to

protect the financial arrangements proposed in this section when arrangements with eligible providers and suppliers are in compliance with this policy and the conditions for use of the Federal anti-kickback statute safe harbor set out at § 1001.952(ii)(1).

We recognize that there are numerous arrangements that IOTA participants may wish to enter other than the financial arrangements described in the proposed regulations for which safe harbor protection may be extended that could be beneficial to the IOTA participants. For example, IOTA participants may choose to engage with organizations that are neither providers nor suppliers to assist with matters such as data analysis; local provider and supplier engagement; care redesign planning and implementation; beneficiary outreach; beneficiary care coordination and management; monitoring IOTA participants' compliance with the model's terms and conditions; or other model-related activities. Such organizations may play important roles in an IOTA participant's plans to implement the model based on the experience these organizations may bring, such as prior experience with living donation initiatives, care coordination expertise, familiarity with a particular local community, or knowledge of SRTR data. We require that all relationships established between IOTA participants and these organizations for purposes of the model would be those permitted only under existing law and regulation, including any relationships that would include the IOTA participant's sharing of model upside risk payments or downside risk payments with such organizations., and must comply with all applicable laws and regulations We require these relationships to be solely based on the level of engagement of the organization's resources to directly support the participants' model implementation.

c. IOTA Collaborators

Given the financial incentives of the IOTA performance-based payments, as described in section III.C.6.c of this final rule, an IOTA participant may want to engage in financial arrangements with providers and suppliers making contributions to the IOTA participant's performance across the achievement domain, efficiency domain, and quality domain. Such arrangements would allow the IOTA participant to share monies earned from the upside risk payments. Likewise, such arrangements could allow the IOTA participant to share the responsibility for the funds needed to repay CMS the downside risk payments. We proposed to use the term ''IOTA collaborator'' to refer to these providers and suppliers.

Because attributed patients include both those on the kidney transplant waitlist and those who have received a kidney transplant, as described in section III.C.4.a of this final rule, many providers and suppliers other than the IOTA participant would furnish related services to attributed patients during the model performance period. As such, for purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), we proposed that the following types of providers and suppliers that are Medicare-enrolled and eligible to participate in Medicare may be IOTA collaborators:

- Nephrologist.
- ESRD Facility.
- Skilled Nursing Facility (SNF).
- Home Health Agency (HHA).
- Long-Term Care Hospital (LTCH).
- Inpatient Rehabilitation Facility (IRF).
- Physician.
- Nonphysician practitioner.
- Therapist in a private practice.
- Comprehensive Outpatient Rehabilitation Facility (CORF).
- Provider or supplier of outpatient therapy services.
- Physician Group Practice (PGP).
- Hospital.
- Critical Access Hospital (CAH).
- Non-physician provider group practice (NPPGP).
- Therapy Group Practice (TGP).

We sought comment on the proposed definition of IOTA collaborators and any additional Medicare-enrolled providers or suppliers that should be included in this definition.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Several commenters supported the inclusion of IOTA collaborators in the model and encouraged expanding the types of entities allowed as IOTA collaborators to include other provider types.

Commenters recommended including in the list of IOTA collaborators: audiologists, registered dietitian nutritionists (RDNs), and rural emergency hospitals.

Response: We thank commenters for their recommendations and support of this initiative. We appreciate your insights on expanding the types of entities allowed as IOTA collaborators. We will take them into consideration in future rulemaking.

After consideration of the public comments received, for the reasons set forth in this rule, we are finalizing the proposal for the model definition of IOTA collaborators as proposed at § 512.402. We are also finalizing as proposed the definitions for the types of IOTA collaborator Medicare-enrolled providers or suppliers at § 512.402 with minor technical corrections to update cross references. Specifically, we are finalizing our proposed definition of nonphysician practitioner at § 512.402 with a minor technical correction to include the full cross reference. Additionally, we are finalizing our proposed definition of therapist at § 512.402 with a minor technical correction to include the correct cross reference to the regulatory definition for that term. Lastly, we are finalizing our proposed definition of hospital at § 512.402 with a technical correction to specify that hospital has the meaning set forth in § 1861(e) of the Act.[327]

d. Sharing Arrangements

(1) General

Similar to the Comprehensive Care for Joint Replacement Payment Model (CJR) (42 CFR part 510), we proposed that certain financial arrangements between an IOTA participant and an IOTA collaborator be termed ''sharing arrangements.'' For purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)), we proposed that a sharing arrangement would be a financial arrangement to share only—(1) the upside risk payment; and (2) the downside risk payment.

Where a payment from an IOTA participant to an IOTA collaborator is made pursuant to a sharing arrangement, we proposed to define that payment as a ''gainsharing payment,'' which is discussed in section III.C.11.d.(3). of this final rule. Where a payment from an IOTA collaborator to an IOTA participant is made pursuant to a sharing arrangement, we proposed to define that payment as an ''alignment payment,'' which is discussed in section III.C.11.d.(3). of this final rule.

We sought comment about all provisions described in the preceding discussion.

We received no comments on these proposals and therefore are finalizing these proposals as proposed in our regulation at § 512.452. We are also finalizing without modification the proposed definitions of sharing

[327] Subsequent to the publication of the proposed rule, we found that the proposed definition of ''hospital'' included an incorrect citation to the Social Security Act. Section 1861(u) of the Act defines ''provider of services,'' which includes more than just hospitals. We clarify that, for the purposes of the IOTA Model, the term ''hospital'' has the meaning set forth in § 1861(e) of the Act.

arrangements, gainsharing payment, and alignment payment at § 512.402.

(2) Requirements

We proposed several requirements for sharing arrangements to help ensure that their sole purpose is to create financial alignment between IOTA participants and IOTA collaborators toward the goals of the model while maintaining adequate program integrity safeguards. An IOTA participant must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. We proposed that a sharing arrangement must comply with the provisions of § 512.452 and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

We proposed that the IOTA participant must develop, maintain, and use a set of written policies for selecting providers and suppliers to be IOTA collaborators. To safeguard against potentially fraudulent or abusive practices, we proposed that the selection criteria must include the quality of care delivered by the potential IOTA collaborator. We also proposed that the selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between, or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent. Additionally, we proposed that IOTA participants must consider the selection of IOTA collaborators based on criteria related to, and inclusive of, the anticipated contribution to the performance of the IOTA participant across the achievement domain, efficiency domain, and quality domain by the potential IOTA collaborator to ensure that the selection of IOTA collaborators takes into consideration the likelihood of their future performance.

It is necessary that IOTA participants have adequate oversight over sharing arrangements to ensure that all arrangements meet the requirements of the model. Therefore, we proposed that the board or other governing body of the IOTA participant have responsibility for overseeing the IOTA participant's participation in the model, including, but not limited to, its arrangements with IOTA collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives (as discussed in III.C.11.g of this final rule).

Finally, we proposed that if an IOTA participant enters a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the model. Requiring oversight of sharing arrangements to be included in the compliance program provides a program integrity safeguard.

We sought comment about all provisions described in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

We proposed that the sharing arrangement must be in writing, signed by the parties, and entered into before care is furnished to attributed patients during the PY under the sharing arrangement. In addition, participation in the sharing arrangement must require the IOTA collaborator to comply with the requirements of this model, as those pertain to their actions and obligations. Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation. It is important that providers and suppliers rendering items and services to attributed patients during the model performance period have the freedom to provide medically necessary items and services to attributed patients without any requirement that they participate in a sharing arrangement to safeguard beneficiary freedom of choice, access to care, and quality of care. The sharing arrangement must set out the mutually agreeable terms for the financial arrangement between the parties to guide and reward model care redesign for future performance across the achievement domain, efficiency domain, and quality domain, rather than reflect the results of model PYs that have already occurred and where the financial outcome of the sharing arrangement terms would be known before signing.

We proposed that the sharing arrangement must require the IOTA collaborator and its employees, contractors (including collaboration agents), and subcontractors to comply with certain requirements that are important for program integrity under the arrangement. We note that the terms contractors and subcontractors, respectively, include collaboration agents as defined later in this section. The sharing arrangement must require all of the individuals and entities in this group to comply with the applicable provisions of §§ 512.450–512.466 of this final rule, including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees, because these individuals and entities all would play a role in model care redesign and be part of financial arrangements under the model. The sharing arrangement must also require all individuals and entities in the group to comply with the applicable Medicare provider enrollment requirements at § 424.500 *et seq.,* including having a valid and active TIN or NPI, during the term of the sharing arrangement. This is to ensure that these individuals and entities have the required enrollment relationship with CMS under the Medicare program, although we note that they are not responsible for complying with requirements that do not apply to them. Finally, the sharing arrangement must require these individuals and entities to comply with all other applicable laws and regulations.

We proposed that the sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care so that financial relationships between IOTA participants and IOTA collaborators do not negatively impact beneficiary protections under the model. The sharing arrangement must require the IOTA collaborator to have, or be covered by, a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the IOTA Model that apply to its role as an IOTA collaborator, including any distribution arrangements, just as we require IOTA participants to have a compliance program that covers oversight of the sharing arrangement for this purpose as a program integrity safeguard. We sought comment on the anticipated effect of the proposed compliance program requirement for IOTA collaborators, particularly with regard to individual physicians and nonphysician practitioners, small PGPs, NPPGPs, and TGPs and whether alternative compliance program requirements for all or a subset of IOTA collaborators should be adopted to mitigate any effect of the proposal that could make participation as an IOTA collaborator infeasible for any provider, supplier, or other entity on the proposed list of types of IOTA collaborators.

For purposes of sharing arrangements under the model, we proposed to define activities related to promoting accountability for the quality, cost, and overall care for attributed patients and performance across the achievement domain, efficiency domain, and quality domain, including managing and

coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; the provision of items and services pre- or post-transplant in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under the model as ''IOTA activities.'' In addition to the quality of episodes of care, we believe the activities that would fall under this proposed definition could encompass the totality of activities upon which it would be appropriate for sharing arrangements to value the contributions of collaborators and collaboration agents toward meeting the performance goals of the model. We sought comment on the proposed definition of IOTA activities as an inclusive and comprehensive framework for capturing direct care and care redesign that contribute to performance across the achievement domain, efficiency domain, and quality domain.

We proposed that the written sharing arrangement agreement must specify the following parameters of the arrangement:

- The purpose and scope of the sharing arrangement.
- The identities and obligations of the parties, including specified IOTA activities and other services to be performed by the parties under the sharing arrangement.
- The date of the sharing arrangement.
- Management and staffing information, including type of personnel or contractors that would be primarily responsible for carrying out IOTA activities.
- The financial or economic terms for payment, including all of the following:

++ Eligibility criteria for a gainsharing payment.

++ Eligibility criteria for an alignment payment.

++ Frequency of gainsharing or alignment payment.

++ Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on performance across the achievement domain, efficiency domain and quality domain, and the provision of IOTA Model activities.

++ Methodology and accounting formula for determining the amount of an alignment payment.

Finally, we proposed to require that the terms of the sharing arrangement must not induce the IOTA participant, IOTA collaborator, or any employees, contractors, or subcontractors of the IOTA participant or IOTA collaborator to reduce or limit medically necessary services to any attributed patient or restrict the ability of an IOTA collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments. These requirements are to ensure that the quality of care for attributed patients is not negatively affected by sharing arrangements under the model.

The proposals for the requirements for sharing arrangements under the model are included in § 512.452.

We sought comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

We received no comments on these proposals and therefore are finalizing these proposals as proposed in our regulation at § 512.452 with slight modifications. Specifically, we are redesignating what was proposed at §§ 512.452(b)(5), (6), (7), and (8) to be §§ 512.452(b)(6), (7), (8), and (9). We are also finalizing without modification the proposed definition of IOTA activities at § 512.402.

(3) Gainsharing Payments and Alignment Payments

We proposed several conditions and limitations for gainsharing payments and alignment payments as program integrity protections for the payments to and from IOTA collaborators. We proposed to require that gainsharing payments be derived solely from upside risk payments; that they be distributed on an annual basis, not more than once per performance year; that they not be a loan, advance payment, or payment for referrals or other business; and that they be clearly identified as a gainsharing payment at the time they are paid.

We believe that gainsharing payment eligibility for IOTA collaborators should be conditioned on two requirements—(1) contributing to performance across the achievement domain, efficiency domain or quality domain; and (2) rendering items and services to attributed patients during the model performance period—as safeguards to ensure that eligibility for gainsharing payments is solely based on aligning financial incentives for IOTA collaborators with the performance metrics of the model. With respect to the first requirement, we proposed that to be eligible to receive a gainsharing payment, an IOTA collaborator must contribute to the performance of the IOTA participant across the achievement domain, efficiency domain or quality domain during the PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment. We also proposed that the contribution to performance across the achievement domain, efficiency domain, or quality domain criteria must be established by the IOTA participant and directly related to the care of attributed patients. With regard to the second requirement, to be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an IOTA collaborator other than a PGP, NPPGP, or TGP must have directly furnished a billable item or service to an attributed patient that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment. For purposes of this requirement, we consider a hospital, CAH or post-acute care provider to have ''directly furnished'' a billable service if one of these entities billed for an item or service for an attributed patient in the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment. The phrase ''PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment'' does not mean the year in which the gainsharing payment was made. These requirements ensure that there is a required relationship between eligibility for a gainsharing payment and the direct care for attributed patients during the PY for these IOTA collaborators. We believe the provision of direct care is essential to the implementation of effective care redesign, and the requirement provides a safeguard against payments to IOTA collaborators other than a PGP, NPPGP, or TGP that are unrelated to direct care for attributed patients during the model performance period.

We proposed to establish similar requirements for IOTA collaborators that are PGPs, NPPGPs and TGPs that vary because these entities do not themselves directly furnish billable services. To be eligible to receive a gainsharing payment or required to make an alignment payment, a PGP, NPPGP or TGP must have billed for an item or service that was rendered by one or more members of the PGP, NPPGP or TGP to an attributed patient that occurred during the same PY for which the IOTA participant earned an upside risk payment that comprises the gainsharing payment or incurred a

downside risk payment. Like the proposal for IOTA collaborators that are not PGPs, NPPGPs or TGPs, these proposals also require a link between the IOTA collaborator that is the PGP, NPPGP or TGP and the provision of items and services to attributed patients during the PY by PGP, NPPGP or TGP members.

Moreover, we further proposed that, because PGPs, NPPGPs and TGPs do not directly furnish items and services to patients, to be eligible to receive a gainsharing payment or be required to make an alignment payment, the PGP, NPPGP or TGP must have contributed to IOTA activities and been clinically involved in the care of attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment. For example, a PGP, NPPGP, or TGP could have contributed to IOTA activities and been clinically involved in the care of attributed patients if they—

- Provided care coordination services to attributed patients during and after inpatient admission;
- Engaged with an IOTA participant in care redesign strategies, and performed a role in the implementation of such strategies, that were designed to improve the quality of care for attributed patients; or
- In coordination with other providers and suppliers (such as PGP members, NPPGP members, or TGP members; the IOTA participant; and post-acute care providers), implemented strategies designed to address and manage the comorbidities of attributed patients.

We proposed to limit the total amount of gainsharing payments for a PY to IOTA collaborators that are physicians, nonphysician practitioners, PGPs, NPPGPs or TGPs. For IOTA collaborators that are physicians or nonphysician practitioners, that limit is 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or nonphysician practitioner to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made. For IOTA collaborators that are PGPs, NPPGPs or TGPs that limit is 50 percent of the Medicare-approved amounts under the PFS for items and services billed by the PGP, NPPGP or TGP and furnished to the IOTA participant's attributed patients by members of the PGP, NPPGP or TGP during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made. These limits are consistent with those in the CJR model.

We proposed that the amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities. The methodology may take into account the amount of such IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators. While we emphasize that financial arrangements may not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent so that their sole purpose is to align the financial incentives of the IOTA participant and IOTA collaborators toward the model, we believe that accounting for the relative amount of IOTA activities by IOTA collaborators in the determination of gainsharing payments does not undermine this objective. Rather, the proposed requirement allows flexibility in the determination of gainsharing payments where the amount of an IOTA collaborator's provision of IOTA activities (including direct care) to attributed patients during the model performance period may contribute to the IOTA participant's upside risk payment that may be available for making a gainsharing payment. Greater contributions of IOTA activities by one IOTA collaborator versus those that result in greater differences in the funds available for gainsharing payments may be appropriately valued in the methodology used to make gainsharing payments to those IOTA collaborators to reflect these differences in IOTA activities among them. For example, a physician who is an IOTA collaborator who treats 20 attributed patients during the PY that result in high quality, less costly care could receive a larger gainsharing payment than a physician who is an IOTA collaborator who treats 10 attributed patients during episodes that similarly result in high quality, less costly care.

However, we do not believe it would be appropriate to allow the selection of IOTA collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment to take into account the amount of IOTA activities provided by a potential or actual IOTA collaborator relative to other potential or actual IOTA collaborators because these financial relationships are not to be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between, or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent. Specifically, with respect to the selection of IOTA collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment, we do not believe that the amount of model activities provided by a potential or actual IOTA collaborator relative to other potential or actual IOTA collaborators could be taken into consideration by the IOTA participant without a significant risk that the financial arrangement in those instances could be based directly or indirectly on the volume or value of referrals or business generated by, between or among the parties. Similarly, if the methodology for determining alignment payments was allowed to take into account the amount of IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators, there would be a significant risk that the financial arrangement could directly account for the volume or value of referrals or business generated by, between, or among the parties and, therefore, we proposed that the methodology for determining alignment payments may not directly take into account the volume or value of referrals or business generated by, between or among the parties.

We sought comment on this proposal for gainsharing payments, where the methodology could take into account the amount of IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators. We also sought comments about whether this standard would provide sufficient additional flexibility in the gainsharing payment methodology to allow the financial reward of IOTA collaborators commensurate with their level of effort that achieves model goals. In addition, we requested comment on whether additional safeguards or a different standard is needed to allow for greater flexibility to provide certain performance-based payments consistent with the goals of program integrity, protecting against abuse and ensuring the goals of the model are met.

We proposed that for each PY, the aggregate amount of all gainsharing payments that are derived from an upside risk payment must not exceed the amount of the upside risk payment

paid by CMS. In accordance with the prior discussion, no entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments, directly or indirectly, on the volume or value of referrals or business otherwise generated by, between, or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent. We proposed that an IOTA participant must not make a gainsharing payment to an IOTA collaborator that is subject to any action for noncompliance with this 42 CFR part 512 or the fraud and abuse laws, or for the provision of substandard care to attributed patients or other integrity problems. Finally, the sharing arrangement must require the IOTA participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on an upside risk payment or was based on the submission of false or fraudulent data. These requirements provide program integrity safeguards for gainsharing under sharing arrangements.

With respect to alignment payments, we proposed that alignment payments from an IOTA collaborator to an IOTA participant may be made at any interval that is agreed upon by both parties. We proposed that alignment payments must not be issued, distributed, or paid prior to the calculation by CMS of a payment amount reflected in a notification of the downside risk payment; loans, advance payments, or payments for referrals or other business; or assessed by an IOTA participant if the IOTA participant does not owe a downside risk payment. The IOTA participant must not receive any amounts under a sharing arrangement from an IOTA collaborator that are not alignment payments.

We also proposed certain limitations on alignment payments that are consistent with the CJR Model. For a PY, the aggregate amount of all alignment payments received by the IOTA participant must not exceed 50 percent of the IOTA participant's downside risk payment. Given that the IOTA participant would be responsible for developing and coordinating care redesign strategies in response to its IOTA participation, we believe it is important that the IOTA participant retain a significant portion of its responsibility for payment to CMS. For example, upon receipt of a notification indicating that the IOTA participant owes a downside risk payment of $100 to CMS, the IOTA participant would be permitted to receive no more than $50 in alignment payments, in the aggregate, from its IOTA collaborators. In addition, the aggregate amount of all alignment payments from a single IOTA collaborator to the IOTA participant may not be greater than 25 percent of the IOTA participant's downside risk payment over the course of a single PY for an IOTA collaborator. We sought comment on our proposed aggregate and individual IOTA collaborator limitations on alignment payments.

We proposed that all gainsharing payments and any alignment payments must be administered by the IOTA participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book). Additionally, we proposed that all gainsharing payments and alignment payments must be made by check, electronic funds transfer (EFT), or another traceable cash transaction. We sought comment on the effect of this proposal.

The proposals for the conditions and restrictions on gainsharing payments and alignment payments under the model are included in § 512.452.

We sought comment about all of the conditions and restrictions set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

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

Comment: A few commenters supported CMS' proposal to allow gainsharing in IOTA but expressed concern regarding the proposed 50 percent cap on shared losses. The commenters recommended that CMS remove the 50 percent cap on shared losses in order to reduce administrative burden for providers, strengthen integration between kidney transplant hospitals and specialists, and maintain consistency with prior models like CJR and BPCI Advanced.

Response: We thank the commenters for their suggestions regarding the proposed 50 percent cap on shared losses. We believe, however, that given that the IOTA participant would be responsible for achieving model goals, it is important that the IOTA participant retain a significant portion of its responsibility for repayment amounts. With that said, we also believe that the 50 percent cap on shared losses supports CMS' goal. However, we will consider this recommendation in future notice and comment rulemaking.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing our proposed provisions for gainsharing payment and alignment payment conditions and limitations in our regulation at § 512.452 with a slight modification. As described and finalized in section III.C.1.a of this final rule, we are finalizing an alternative model start date of July 1, 2025. As such, we are also finalizing a slight modification to the definition of performance year (PY) to mean a 12-month period beginning on July 1 and ending on June 30 of each year during the model performance period, as described and finalized in section III.C.1.a of this final rule. Accordingly, we are modifying the regulation at § 512.452(c)(1)(ii) to remove reference to a calendar year and specify that gainsharing payments and alignment payments must be distributed on an annual basis (not more than once per performance year).

(4) Documentation Requirements

To ensure the integrity of the sharing arrangements, we proposed that IOTA participants must meet a variety of documentation requirements for these arrangements. Specifically, the IOTA participant must—

- Document the sharing arrangement contemporaneously with the establishment of the arrangement;
- Maintain accurate current and historical lists of all IOTA collaborators, including IOTA collaborator names and addresses. Specifically, the IOTA participant must—

++ Update such lists on at least a quarterly basis; and

++ Publicly report the current and historical lists of IOTA collaborators and any written policies for selecting individuals and entities to be IOTA collaborators required by the IOTA participant on a web page on the IOTA participant's website; and

- Maintain and require each IOTA collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum the—

++ Nature of the payment (gainsharing payment or alignment payment);

++ Identity of the parties making and receiving the payment;

++ Date of the payment;

++ Amount of the payment;

++ Date and amount of any recoupment of all or a portion of an IOTA collaborator's gainsharing payment; and

++ Explanation for each recoupment, such as whether the IOTA collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of an upside risk payment, or was based on the submission of false or fraudulent data.

In addition, we proposed that the IOTA participant must keep records for all of the following:

- Its process for determining and verifying its potential and current IOTA collaborators' eligibility to participate in Medicare;
- A description of current health information technology, including systems to track upside risk payments and downside risk payments; and
- Its plan to track gainsharing payments and alignment payments.

Finally, we proposed that the IOTA participant must retain and provide access to, and must require each IOTA collaborator to retain and provide access to, the required documentation in accordance with § 512.460 and § 1001.952(ii).

The proposals for the requirements for documentation of sharing arrangements under the model are included in § 512.452(d).

We sought comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

We received no comments on these proposals and therefore are finalizing these proposals as proposed in our regulation at § 512.452.

e. Distribution Arrangements

(1) General

Similar to the CJR Model, we proposed that certain financial arrangements between IOTA collaborators and other individuals or entities called ''collaboration agents'' be termed ''distribution arrangements.'' For purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)), we proposed to define ''distribution arrangement'' as a financial arrangement between an IOTA collaborator that is a PGP, NPPGP or TGP and a collaboration agent for the sole purpose of sharing a gainsharing payment received by the PGP, NPPGP or TGP. We proposed to define ''collaboration agent'' as an individual or entity that is not an IOTA collaborator and that is a member of a PGP, NPPGP, or TGP that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is an IOTA collaborator. Where a payment from an IOTA collaborator that is an PGP, NPPGP, or TGP is made to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments, we proposed to define that payment as a ''distribution payment.'' We proposed that a collaboration agent could only make a distribution payment in accordance with a distribution arrangement that complies with the provisions of § 512.454 and all other applicable laws and regulations, including the fraud and abuse laws.

The proposals for the general provisions for distribution arrangements under the model are included in § 512.454.

We sought comment about all of the provisions set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

We received no comments on these proposals and therefore are finalizing these proposals as proposed in our regulation at § 512.454. We are also finalizing without modification the proposed definitions of distribution arrangement, collaboration agent, and distribution payment at § 512.402.

(2) Requirements

We proposed a number of specific requirements for distribution arrangements as a program integrity safeguard to help ensure that their sole purpose is to create financial alignment between IOTA collaborators and collaboration agents and performance across the achievement domain, efficiency domain, and quality domain. These requirements largely parallel those proposed in § 512.452 for sharing arrangements and gainsharing payments based on similar reasoning for these two types of arrangements and payments. We proposed that all distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to attributed patients under the distribution arrangement. Furthermore, we proposed that participation must be voluntary and without penalty for nonparticipation, and the distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

Like our proposal for gainsharing payments, we proposed that the opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent. We proposed more flexible standards for the determination of the amount of distribution payments from PGPs, NPPGPs and TGPs for the same reasons we proposed this standard for the determination of gainsharing payments.

We note that for distribution payments made by a PGP to PGP members, by NPPGPs to NPPGP members, or by TGPs to TGP members, the requirement that the amount of any distribution payments must be determined in accordance with a methodology that is substantially based on performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities may be more limiting in how a PGP pays its members than is allowed under existing law. Therefore, to retain existing flexibility for distribution payments by a PGP to PGP members, we proposed that the amount of the distribution payment from a PGP to PGP members must be determined in a manner that complies with § 411.352(g) or in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities and that may take into account the amount of such IOTA activities provided by a collaboration agent relative to other collaboration agents. The former option may allow a PGP to provide its members a financial benefit through the model without consideration of the PGP member's individual contribution to performance across the achievement domain, efficiency domain and quality domain, and PGP members that are not collaboration agents (including those who furnished no services to attributed patients) would be able to receive a share of the profits from their PGP that includes the monies contained in a gainsharing payment. We believe this is an appropriate exception to the general standard for determining the amount of a distribution payment under the model from a PGP to a PGP member, because CMS has determined under the physician self-referral law that payments from a group practice as defined under § 411.352 to its members that comply with § 411.352(g) are appropriate.

We sought comment on this proposal and specifically on whether there are additional safeguards or a different

standard is needed to allow for greater flexibility in calculating the amount of distribution payments that would avoid program integrity risks and whether additional or different safeguards are reasonable, necessary, or appropriate for the amount of distribution payments from a PGP to its members, a NPPGP to its members or a TGP to its members.

Similar to our proposed requirements for sharing arrangements for those IOTA collaborators that furnish or bill for items and services, except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), we proposed that a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to an attributed patient during the same PY for which the IOTA participant earned the upside risk payment. We note that all individuals and entities that fall within our proposed definition of collaboration agent may either directly furnish or bill for items and services rendered to attributed patients. This proposal ensures that, absent the alternative safeguards afforded by a PGP's distribution payments in compliance with § 411.352(g), there is the same required relationship between direct care for attributed patients during the PY and distribution payment eligibility that we require for gainsharing payment eligibility. We believe this requirement provides a safeguard against payments to collaboration agents that are unrelated to direct care for attributed patients during the PY when the amount of the distribution payment is not determined in a manner that complies with § 411.352(g).

Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), we proposed the same limitations on the total amount of distribution payments to physicians, nonphysician practitioners, PGPs, NPPGPs and TGPs as we proposed for gainsharing payments. In the case of a collaboration agent that is a physician or nonphysician practitioner, we proposed to limit the total amount of distribution payments paid for a PY to the collaboration agent to 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed. In the case of a collaboration agent that is a group practice, we proposed that the limit would be 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the group practice for items and services furnished by members of the group practice to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed. We believe that, absent the alternative safeguards afforded by a group practice's distribution payments in compliance with § 411.352(g), these proposed limitations on distribution payments, which are the same as those for gainsharing payments to physicians, nonphysician practitioners, and group practices, are necessary to eliminate any financial incentives for these individuals or entities to engage in a financial arrangement as an IOTA collaborator versus as a collaboration agent. Furthermore, we believe that group practices should be able to choose whether to engage in financial arrangements directly with IOTA participants as IOTA collaborators without having a different limit on their maximum financial gain from one arrangement versus another.

We further proposed that with respect to the distribution of any gainsharing payment received by a PGP, NPPGP or TGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the IOTA collaborator from the IOTA participant. Like gainsharing and alignment payments, we proposed that all distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments. Finally, the distribution arrangement must not induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We proposed that the IOTA collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.454, including—

- The relevant written agreements;
- The date and amount of any distribution payment(s);
- The identity of each collaboration agent that received a distribution payment; and
- A description of the methodology and accounting formula for determining the amount of any distribution payment.

We proposed that the IOTA collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same IOTA participant. This proposal ensures that the proposed separate limitations on the total amount of gainsharing payment and distribution payment to PGPs, NPPGPs, TGPs, physicians, and nonphysician practitioners that are substantially based on performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities are not exceeded in absolute dollars by a PGP, NPPGP, TGP, physician, or nonphysician practitioner's participation in both a sharing arrangement and distribution arrangement for the care of the same IOTA beneficiaries during the PY. Allowing both types of arrangements for the same individual or entity for care of the same attributed patients during the PY could also allow for duplicate counting of the individual or entity's same contribution to the achievement domain, efficiency domain, and quality domain and provision of IOTA Model activities in the methodologies for both gainsharing and distribution payments, leading to financial gain that is disproportionate to the contribution to the achievement domain, efficiency domain and quality domain and provision of IOTA Model activities by that individual or entity. Finally, we proposed that the IOTA collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.460.

The proposals for requirements for distribution arrangements under the model are included in § 512.454.

We sought comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met. In addition, we sought comment on how the regulation of the financial arrangements under this proposal may interact with how these or similar financial arrangements are regulated under the Medicare Shared Savings Program.

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

Comment: A commenter expressed support for the proposal that the Federal anti-kickback statute safe harbor be made available to IOTA participants and their IOTA collaborators.

Response: We thank the commenter for their support.

After consideration of the public comment we received, we are finalizing our proposals regarding the requirements for distribution arrangements without modification in our regulation at § 512.454.

f. Enforcement Authority

OIG authority is not limited or restricted by the provisions of the model, including the authority to audit, evaluate, investigate, or inspect the IOTA participant, IOTA collaborators, collaboration agents, or any other person or entity or their records, data, or information, without limitations. Additionally, no model provisions limit or restrict the authority of any other Government Agency to do the same. The proposals for enforcement authority under the model are included in § 512.455.

We sought comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

We received no comments on these proposals. These proposals are finalized at § 512.455 with slight modification to remove a stray reference to the CJR Model at § 512.455(b).

g. Attributed Patient Engagement Incentives

We believed it was necessary and appropriate to provide additional flexibilities to IOTA participants for purposes of testing the IOTA Model to give IOTA participants additional access to the tools necessary to improve attributed patients' access to kidney transplants and ensure attributed patients receive comprehensive and patient-centered post-transplant care. As discussed in section III.C.11.i. of this final rule, CMS made a determination that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives is available to protect Part B and Part D immunosuppressive drug cost sharing support and attributed patient engagement incentives finalized in this section when the incentives are offered in compliance with this policy, specifically the conditions for use of the Federal anti-kickback statute safe harbor set out at § 1001.952(ii)(2).

(1) Part B and Part D Immunosuppressive Drug Cost Sharing Support

The cost of immunosuppressive drugs is a financial burden for many transplant recipients, particularly those without sufficient health insurance coverage.[328] A person's ability to pay for immunosuppressive drugs, among other services needed in the perioperative and postoperative periods, is a factor used by transplant hospitals to assess suitability for the transplant waitlist.[329] Studies have found that low income status decreases the likelihood of waitlisting.[330] One survey of transplant programs found that 67.3 percent of programs surveyed reported frequent or occasional failure to list patients due to concerns regarding ability to pay for immunosuppressive medications.[331] In assessing the financial implications of extending Medicare coverage of immunosuppressive drugs for the lifetime of the patient, the Assistant Secretary for Planning and Evaluation (ASPE) assumed a non-adherence graft failure rate of 10.7 percent and assessed that factors outside of affordability had minimal impact on non-adherence to immunosuppressive drugs.[332]

Between 2016 and 2019, immunosuppressive drugs represented the greatest proportion of drug expenditures in the year following kidney transplant in Medicare Parts B and D.[333] Between 2016 and 2019, the Per-Patient-Per-Year expenditure in the year following transplant in Medicare Parts B and D was $6,947.[334] Medicare beneficiaries whose immunosuppressive drugs are covered by Part B are responsible for 20 percent of these costs. The cost sharing obligation of Medicare beneficiaries whose immunosuppressive drugs are covered by Part D can vary depending on the benefit structure of the Part D plan.

At § 512.456 of the proposed rule, we proposed to allow IOTA participants to subsidize, in whole or in part, the cost sharing associated with immunosuppressive drugs covered by Part B, the Part B Immunosuppressive Drug (Part B ID) benefit, and Part D (''Part B and Part D immunosuppressive drug cost sharing support'') incurred by attributed patients. As discussed in section III.C.11.i. of this final rule, CMS has made a determination that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect the subsidy of cost sharing obligations that are made in compliance with this policy and the conditions for use of the Federal anti-kickback statute safe harbor set out at § 1001.952(ii)(2).

As stated in the proposed rule, we expect that a large proportion of an IOTA participant's attributed patient population would be Medicare ESRD beneficiaries, covered either by traditional Medicare or by MA (89 FR 43518). Most ESRD beneficiaries covered by traditional Medicare receive immunosuppressive drug coverage through Part B. A proportion of ESRD beneficiaries who are not eligible for Part A at the time of the kidney transplant or who receive a kidney transplant in a non-Medicare approved facility receive immunosuppressive drugs through Medicare Part D. ESRD beneficiaries covered by MA receive Part B immunosuppressive drugs through the plan in which the beneficiary is enrolled.

To be eligible for Part B and Part D immunosuppressive drug cost sharing support, at § 512.402 of the proposed rule, we proposed to define eligible attributed patient as an attributed patient that receives immunosuppressive drug coverage through Part B or Part D but that does not have secondary insurance that could provide cost sharing support. An IOTA participant's attributed patient population could include several subsets of eligible attributed patients. One subset of eligible attributed patients could be ESRD beneficiaries who are not able to purchase secondary insurance due to State laws that do not require insurers to sell Medigap plans to Medicare Beneficiaries under the age of 65. Another subset of eligible attributed patients could, under certain conditions, be ESRD beneficiaries whose eligibility for Medicare only due to ESRD ends 36 months following a kidney transplant. Attributed patients whose eligibility for Medicare due to ESRD ends 36 months following a

[328] James, A., & Mannon, R.B. (2015). The Cost of Transplant Immunosuppressant Therapy: Is This Sustainable? *Current Transplantation Reports, 2*(2), 113–121. *https://doi.org/10.1007/s40472-015-0052-y.*

[329] *The kidney transplant waitlist.* (n.d.). Transplant Living. *https://transplantliving.org/kidney/the-kidney-transplant-waitlist/.*

[330] 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.*

[331] Evans, R.W., Applegate, W.H., Briscoe, D.M., Cohen, D.J., Rorick, C.C., Murphy, B.T., & Madsen, J.C. (2010). Cost-related immunosuppressive medication nonadherence among kidney transplant recipients. *Clinical Journal of the American Society of Nephrology, 5*(12), 2323–2328. *https://doi.org/10.2215/cjn.04220510.*

[332] *Assessing the Costs and Benefits of Extending Coverage of Immunosuppressive Drugs under Medicare.* (n.d.). ASPE. *https://aspe.hhs.gov/reports/assessing-costs-benefits-extending-coverage-immunosuppressive-drugs-under-medicare.*

[333] United States Renal Data System. (2022). 2022 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD. *https://usrds-adr.niddk.nih.gov/2022.*

[334] Ibid.

kidney transplant may be eligible for the Part B–ID benefit depending on the availability of other health coverage options such as Medicaid, plans purchased via a State health exchange, or the TRICARE for Life program. Other attributed patients whose Medicare eligibility due to ESRD concludes 36 months following a transplant could choose to return to work and receive immunosuppressive drug coverage through an Employer Group Health Plan (EGHP), enroll in a Qualified health plan (QHP) under the Affordable Care Act as defined by 45 CFR 155.20, or receive coverage through Medicaid. These attributed patients would not be eligible for Part B and Part D immunosuppressive drug cost sharing support. We believed that Part B and Part D immunosuppressive drug cost sharing support would have special value for attributed patients whose Medicare eligibility due only to ESRD ends after 36 months and who are eligible for Medicare Savings Programs (MSPs) but who live in States that have not expanded Medicaid eligibility for adults to include certain individuals with incomes up to 138 percent of the Federal Poverty Level (FPL). These individuals may have incomes that are too high to qualify for Medicaid, but too low to qualify for advance premium tax credits (APTCs) or cost-sharing reductions (CSRs) that would allow them to purchase a QHP. We did not propose that Part B and Part D immunosuppressive drug cost sharing support would count towards an eligible attributed patients' Part D True Out-of-Pocket (TrOOP). Part B and Part D immunosuppressive drug cost sharing support would be reported on the Prescription Drug Event (PDE) record as Patient Liability Reduction due to Other Payer Amount (PLRO) (89 FR 43518).

At § 512.456(a) of the proposed rule, we proposed to allow IOTA participants to subsidize, in whole or in part, the cost sharing associated with immunosuppressive drugs covered by Part B, the Part B–ID benefit, and Part D because we believed cost sharing associated with medically necessary immunosuppressive drugs would represent a significant out-of-pocket cost burden to attributed patients who receive immunosuppressive drug coverage through Part B, the Part B–ID benefit, or Part D, and because we believed an IOTA participant's attributed patient population would include beneficiaries whose immunosuppressive drugs are covered through each of these avenues (that is, Part B, the Part B–ID benefit, and Part D).

At § 512.456(a) of the proposed rule, we proposed several safeguards for the proposed Part B and Part D immunosuppressive drug cost sharing support policy. First, an attributed patient must be eligible to receive cost sharing support under the Part B and Part D cost sharing support policy. IOTA participants must provide a written policy for Part B and Part D immunosuppressive drug cost sharing support in a form and manner determined by CMS that is approved by CMS prior to the PY in which the cost sharing support would be available and prior to offering attributed patients the incentive. An IOTA participant would be required to revalidate the written policy with CMS in a form and manner determined by CMS prior to each PY in which Part B and Part D immunosuppressive drug cost sharing support would be offered subsequently. The initial written policy and the policy that would be revalidated by CMS must establish and justify the criteria that qualify an eligible attributed patient to receive Part B and Part D immunosuppressive drug cost sharing support. In providing the written policy and the revalidation of the written policy for Part B and Part D immunosuppressive drug cost sharing support, the IOTA participant must attest that the IOTA participant will not, in providing Part B and Part D immunosuppressive drug cost sharing support, take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patient's choice of pharmacy. We believed these policies were necessary to ensure that an IOTA participant would have a sound basis for determining eligibility requirements for Part B and Part D immunosuppressive drug cost sharing support.

At § 512.456(b) of the proposed rule, we proposed safeguards to protect against an IOTA participant preferentially providing cost sharing support for certain immunosuppressive drugs. An IOTA participant must not take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patients' choice of pharmacy when providing Part B and Part D immunosuppressive drug cost sharing support. In addition, an IOTA participant must not accept financial or operational support for the Part B and Part D immunosuppressive drug cost sharing support from pharmacies and pharmaceutical manufacturers. Immunosuppressive drug regimens are adjusted to an individual's unique clinical characteristics to achieve a balance between preserving the health of the transplanted organ and reducing morbidity associated with long-term immunosuppression. We did not believe that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives should be used to protect arrangements that could limit or influence attributed patients' access to the most clinically appropriate immunosuppressive drugs. Finally, to facilitate compliance monitoring, we proposed that IOTA participants must maintain documentation regarding this beneficiary incentive. At minimum, the IOTA participant must maintain contemporaneous documentation that includes the identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided, the date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided, and the amount or amounts of Part B and Part D immunosuppressive drug cost sharing support that was provided. IOTA participants must retain and provide access to the required documentation consistent with section III.C.12 and § 1001.952(ii)(2).

We considered alternative safeguards for the Part B and Part D immunosuppressive drug cost sharing support policy (89 FR 43518). We considered requiring that an IOTA participant that wishes to offer Part B and Part D immunosuppressive drug cost sharing support must offer it to every attributed patient whose immunosuppressive drugs are covered by Part B or Part D and who does not have secondary insurance (89 FR 43518). Ultimately, we believed such a policy would run counter to our intention to offer IOTA participants flexibility to meet the needs of their attributed patient populations.

We also considered alternatives to the entirety of the proposed Part B and Part D immunosuppressive drug cost sharing support policy (89 FR 43594). We considered waiving Medicare payment requirements such that CMS would pay the full amount of the Part B or Part B–ID coinsurance for immunosuppressive drugs that are medically necessary for preventing or treating the rejection of a transplanted organ or tissue. If we were to pay 100 percent of the cost of immunosuppressive drugs for attributed patients who are Medicare beneficiaries whose immunosuppressive drugs are covered by Part B and attributed patients whose immunosuppressive drugs are covered by the Part B–ID benefit, such attributed patients would have no cost sharing obligation.

However, we believed that this policy would represent too large an impact to the IOTA Model savings estimates, and thus would potentially jeopardize our ability to continue to test the IOTA Model, if such a policy were finalized.

We also considered waiving the premium for the Part B–ID benefit (89 FR 43595). Under section 402(d) of the CAA and the implementing regulations at 42 CFR 408.20(f), the Secretary determines and promulgates a monthly premium rate for individuals enrolled in the Part B–ID benefit that is 15 percent of the monthly actuarial rate for beneficiaries who are age 65 and older. The Part B premium for 2024 for individuals enrolled in the Part B–ID benefit who file individual or joint tax returns with a modified adjusted gross income of less than or equal to $103,000 or $206,000 respectively, is $103.00. The Part B–ID premium is subject to income-related adjustments based on modified adjusted gross income. We believed the Part B–ID benefit monthly premium may represent a substantial out-of-pocket expenditure for individuals enrolled in the benefit given that it is prudent for the individual to acquire additional health insurance to cover other necessary health care services outside of immunosuppressive drugs. A premium waiver for the Part B–ID benefit is authorized by section 1115A(d)(1) of the Act, under which the Secretary may waive provisions of Title XVIII of the Act, including provisions of section 1836(b) of the Act, as may be necessary solely for purposes of carrying out section 1115A of the Act. We believed, however, that waiving the premium for the Part B–ID benefit would have too significant an impact on the IOTA Model savings estimates; therefore, we are not proposing to waive it for purposes of the IOTA Model.

We sought feedback on the proposal to allow an IOTA participant to subsidize the 20 percent coinsurance on immunosuppressive drugs covered by Part B or the Part B–ID benefit and the cost sharing associated with immunosuppressive drugs covered by Part D, when an attributed patient is eligible, meaning the attributed patient does not have secondary insurance and meets the eligibility criteria defined by the IOTA participant and approved by CMS prior to the PY in which the cost sharing support is provided. We also solicited input from interested parties on additional patient-centered safeguards that we may consider protecting cost sharing subsidies made under the proposed Part B and Part D immunosuppressive drug cost sharing support policy, if finalized.

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

Comment: Several commenters expressed support to provide cost sharing for immunosuppressive drugs covered under Part B and Part D to ensure long term success of kidney transplants.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern with the Part B and Part D drug cost-sharing provision, as it could incentivize patient choice of kidney transplant hospital, disadvantage patients with other insurance, create logistical challenges, and create significant financial burden for IOTA participants.

Response: We thank the commenters for their feedback. We understand the concerns about possible incentivization of patient choice of kidney transplant hospital but believe patient choice is adequately protected in the provision to be finalized. First, and most importantly, we note that providers and suppliers are still required to provide all medically necessary services to beneficiaries, and that this model does not change beneficiary access to services, providers, or suppliers. Second, we note that there are already policies in other models that include similar incentives. We also understand the possible disadvantage to patients with other insurance. We expect that a large portion of the IOTA participant's attributed patient population would be Medicare ESRD beneficiaries, covered by traditional Medicare, so any possible impact would be mitigated as there would be only a small number of patients with other insurance. We also believe that the safeguards that we have put into place, such as the written policy requirements, will limit these concerns as we will be monitoring the provision of any incentives.

We also understand the concerns about the potential burdens these incentives may place on IOTA participants. IOTA participants can choose whether to offer the Part B and Part D drug cost-sharing provision. As such, if the logistical challenges and financial burden for transplant hospitals exceeds the benefits for the IOTA participants, then the benefit does not need to be provided. Our goal is to ensure that beneficiary incentives effectively support patient care without imposing unnecessary burdens on IOTA participants. We are finalizing this policy as proposed. However, we appreciate these insights and will take them into account in future rulemaking cycles.

Comment: Several commenters suggested the cost-sharing provision should include additional metrics such as allowing the Part B copay to count towards out-of-pocket maximum, allowing IOTA participants to have the cost sharing total be offset in part or whole, and track the effectiveness of cost sharing on patient care.

Response: We thank the commenters for their suggestion. We did not propose that Part B and Part D immunosuppressive drug cost sharing support would count towards an eligible attributed patients' Part D True Out-of-Pocket (TrOOP). Part B and Part D immunosuppressive drug cost sharing support would be reported on the Prescription Drug Event (PDE) record as Patient Liability Reduction due to Other Payer Amount (PLRO). We believe that as these costs are not being expended by the attributed patients themselves but rather by the IOTA participant, that it would contravene the purposes behind the TrOOP.

Neither allowing IOTA participants to have the cost sharing total to be offset nor tracking the effectiveness of cost sharing on patient care were included in the proposed rule, and we therefore are not finalizing this expansion suggested by the commenters in this final rule. We will take the commenters' feedback into consideration as we consider potential future changes to the model design.

Comment: A few commenters suggested CMS should provide full cost coverage for Part B and Part D immunosuppressive drugs for all patients included on the low-income list.

Response: We thank the commenters for their suggestion. We considered waiving Medicare payment requirements such that we would pay the full amount of the Part B or Part D coinsurance for immunosuppressive drugs that are medically necessary for preventing or treating the rejection of a transplanted organ or tissue. We believe that covering the cost even for the subset of patients who qualify as low-income would represent too large an impact to the IOTA Model savings estimates, and thus would potentially jeopardize our ability to continue to test the IOTA Model. As such, we determined that a cost support subsidy rather than a reduction would meet the objectives of this model.

Comment: A few commenters suggested the provision should include other related services, such as anti-viral, blood pressure and diabetes medications, blood and urine testing, and office visits.

Response: We thank the commenters for their suggestion. The suggested

expansion of other related services, such as anti-viral, blood pressure and diabetes medications, blood and urine testing, and office visits, was not included in the proposed rule, and we therefore are not finalizing this expansion suggested by the commenters in this final rule. We will take the commenters' feedback into consideration as we consider potential future changes to the model design.

After consideration of the public comments we received, we are finalizing our proposed provision for the Part B and Part D immunosuppressive drug cost sharing support beneficiary incentive as proposed, with a minor technical correction to update the section numbering in our regulation at § 512.456. We are finalizing the proposed definition of eligible attributed patient at § 512.402 with a minor technical correction to address a typographical error by inserting the word ''drug'' in ''immunosuppressive drug coverage.'' We are also finalizing the proposed definition of Part B and Part D immunosuppressive drug cost sharing support at § 512.402 with a minor technical correction to update the cross reference. Specifically, we are removing the cross reference to § 512.458 and replacing it to reflect § 512.456.

(2) Attributed Patient Engagement Incentives

We believed that providing additional flexibilities under the IOTA Model would allow IOTA participants to support attributed patients in overcoming challenges associated with remaining active on the kidney transplant waitlist and adhering to comprehensive post-transplant care. Thus, at § 512.458(a) of the proposed rule, we proposed that IOTA participants may offer the following attributed patient engagement incentives under certain circumstances:

- Communication devices and related communication services directly pertaining to communication with an IOTA participant or IOTA collaborator to improve communication between an attributed patient and an IOTA participant or IOTA collaborator;
- Transportation to and from a transplant hospital that is an IOTA participant and between other providers and suppliers involved in the provision of ESRD care;
- Mental health services to address an attributed patient's behavioral health symptoms pre- and post-transplant; and
- In-home care to support the health of the attributed patient or the kidney transplant in the post-transplant period.

For the purposes of the proposed attributed patient engagement incentives, at § 512.402 of the proposed rule, we defined post-transplant period to mean the 90-day period following an attributed patient's receipt of a kidney transplant. We proposed a 90-day post-transplant period because it may take up to 3 months for many individuals to fully recover from a kidney transplant.[335] At § 512.458(b) of the proposed rule, we proposed that attributed patient engagement incentives that are communication devices and related communication services, transportation to and from an IOTA participant and between other providers and suppliers involved in the provision of ESRD care, and mental health services to address an attributed patient's behavioral health symptoms could, under certain circumstances described in this section, be offered while an attributed patient is on a waitlist, after an attributed patient receives a transplant, or both. In-home care to support the health of the attributed patient or the kidney transplant may only be offered in the post-transplant period.

A mixed methods study of transplant providers' assessment of barriers to accessing a kidney transplant found that transportation was the most reported impediment to transplant (89 FR 43518).[336] Interested parties have informed us that transportation to medical appointments pre- and post-transplant, as well as to and from the dialysis center for treatments pre-transplant, is an important factor in maintaining active status on the list and the health of an individual and the graft after the transplant. Interested parties have also communicated with us about the importance of communication with waitlisted patients. We understood it can be common for an individual to not receive important information about the kidney transplant process when transplant hospitals and dialysis facilities do not communicate with one another about a patient's status. We believed we may be able to overcome this challenge by providing IOTA participants with greater flexibility to communicate directly with attributed patients about their status in the kidney transplant process.[337] [338] We understood that attributed patients who face communication and transportation barriers while on the kidney transplant waitlist may be inactivated, meaning that the attributed patient cannot receive organ offers (89 FR 43518). An attributed patient that cannot receive organ offers is misaligned with the IOTA Model's proposed performance assessment methodology, which would encourage an IOTA participant to increase its number of transplants. An attributed patient that cannot receive organ offers represents a missed opportunity for transplant, which is inconsistent with the goals of the proposed IOTA Model. Accordingly, we were interested in providing a framework under which an IOTA participant would be able to offer attributed patient engagement incentives in the form of communication devices and related communication services may increase the number of attributed patients who achieve and maintain active status on the kidney transplant waitlist. We believed the availability of transportation to and from an IOTA participant and between other providers and suppliers involved in the provision of ESRD care and mental health services to address an attributed patient's behavioral health symptom may also act in service of assisting more attributed patients in overcoming barriers to achieving or maintaining active status on a waitlist, among other challenges in the kidney transplant process prior to and after receiving a kidney transplant.

For example, we were also interested in providing greater flexibility to IOTA participants to support improved adherence to processes of care pre- and post-transplant that may support the ability of an attributed patient to accept an organ offer and the outcomes of the attributed patient and the graft after receiving a kidney transplant. Anxiety and depression may increase as attributed patients spend time on the kidney transplant waitlist.[339] Prevalence of depression is reported to decrease after kidney transplant, but may still

[335] *Recovery after transplant surgery | American Kidney Fund.* (2021, December 14). *www.kidneyfund.org. https://www.kidneyfund.org/kidney-donation-and-transplant/life-after-transplant-rejection-prevention-and-healthy-tips/recovery-after-transplant-surgery.*

[336] Browne, T., McPherson, L., Retzloff, S., Darius, A., Wilk, A.S., Cruz, A., Wright, S., Pastan, S.O., Gander, J.C., Berlin, A.A., & Patzer, R.E. (2021). Improving access to kidney transplantation: Perspectives from Dialysis and Transplant Staff in the Southeastern United States. Kidney Medicine, 3(5). *https://doi.org/10.1016/j.xkme.2021.04.017.*

[337] *Ibid.*

[338] Gillespie, A. (2021). Communication breakdown: Improving communication between transplant centers and dialysis facilities to improve access to kidney transplantation. Kidney Medicine, 3(5), 696–698. *https://doi.org/10.1016/j.xkme.2021.08.003.*

[339] Corruble, E., Durrbach, A., Charpentier, B., Lang, P., Amidi, S., Dezamis, A., Barry, C., & Falissard, B. (2010). Progressive increase of anxiety and depression in patients waiting for a kidney transplantation. Behavioral Medicine, 36(1), 32–36. *https://doi.org/10.1080/08964280903521339.*

exceed 20 percent.[340] Interested parties have reported that behavioral health symptoms interfere with adherence to care recommendations, including activities that support remaining active on the transplant waitlist and behaviors that support positive clinical outcomes for the patient and the graft after the kidney transplant procedure. Interested parties have also informed us of the importance of a transplant recipient having the support of another person in the home for a short period in the post-transplant period to enhance recovery.

We also believed providing the option for flexibility to offer attributed patient engagement incentives under the auspices of the IOTA Model would allow IOTA participants to provide attributed patients with tools to overcome barriers in the process of receiving a kidney transplant, thereby increasing adherence to the kidney transplant process, improving post-transplant outcomes, and supporting patient-centricity in the IOTA Model. As stated in section III.C.11.i. of this final rule, we made the determination that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect the attributed patient engagement incentives proposed in this section when the incentives are offered or given to the attributed patient solely when the remuneration is exchanged between an IOTA participant and an attributed patient in compliance with the requirements of § 512.459 and the conditions of the safe harbor for CMS-sponsored model patient incentives.

At § 512.458(b) of the proposed rule, we proposed programmatic requirements for the attributed patient engagement incentives. First, an IOTA participant must provide a written policy in a form and manner determined by CMS for the provision of attributed patient engagement incentives. The IOTA participant's written policy must be approved by CMS before the PY in which an attributed patient engagement incentive is first made available, and must be revalidated by CMS, in a form and manner specified by CMS, prior to each PY in which an IOTA participant wishes to offer an attributed patient engagement incentive subsequently. The IOTA participant's written policy must describe the items or services the IOTA participant plans to provide, an explanation of how each item or service that would be an attributed patient engagement incentive has a reasonable connection to, at minimum, one of the following: (1) achieving or maintaining active status on a kidney transplant waitlist; (2) accessing the kidney transplant procedure; or (3) the health of the attributed patient or the kidney transplant in the post-transplant period, and a justification for the need for the attributed patient engagement incentives that is specific to the IOTA participant's attributed patient population. The IOTA participant's written policy must also include an attestation that items that are attributed patient engagement incentives would be provided directly to an attributed patient, meaning that third parties would be precluded from providing an item that is an attributed patient engagement incentive to an attributed patient. We are not requiring an IOTA participant to provide any such attestation pertaining to services that are attributed patient engagement incentives because we acknowledge that services such as communication services, mental health services and in-home care services are generally provided by third parties. The IOTA participant would, however, be required to attest in its written policy that the IOTA participant would pay the service provider directly for services. Finally, the IOTA participant's written policy must also include an attestation that any items or services acquired by the IOTA participant that would be furnished as attributed patient engagement incentives would be acquired for the minimum amount necessary for an attributed patient to achieve or maintain active status on the kidney transplant waitlist, access the kidney transplant procedure, or support the health of the attributed patient or the kidney transplant in the post-transplant period.

At § 512.458(c) of the proposed rule, we proposed the following restrictions on the provision of attributed patient engagement incentives. An IOTA participant must provide items that are attributed patient engagement incentives must be provided directly to an attributed patient and an IOTA participant must pay a service provider directly for any services that are offered as attributed patient engagement incentives. An IOTA participant must not offer attributed patient engagement incentives that are tied to the receipt of items of services from a particular provider or supplier or advertise or promote items or services that are attributed patient engagement incentives, except to make an attributed patient aware of the availability of the items or services at the time an attributed patient could reasonably benefit from them. An IOTA participant must not receive donations directly or indirectly to purchase attributed patient engagement incentives. Finally, items that are attributed patient engagement incentives must be retrieved from the attributed patient when the attributed patient is no longer eligible for that item or at the conclusion of the IOTA Model, whichever is earlier. Documented, diligent, good faith attempts to retrieve items that are attributed patient engagement incentives are deemed to meet the retrieval requirement.

At § 512.458(c) of the proposed rule, we proposed the following, additional restrictions pertaining to attributed patient engagement incentives that are communication devices, because we believe that such items may be especially susceptible to abuse. An IOTA participant's purchase of items that are communication devices must not exceed $1000 in retail value for any one attributed patient in any one PY. Items that are communication devices must remain the property of the IOTA participant. An IOTA participant must retrieve the item that is a communication device either when the attributed patient is no longer eligible for the communication device or at the conclusion of the IOTA Model, whichever is earlier. Items that are communication devices must be retrieved from an attributed patient before another communication device may be provided to the same attributed patient. This restriction applies across PYs. In other words, an IOTA participant may not offer another communication device to the same attributed patient across all IOTA Model years until the first communication device has been retrieved. We believed these additional restrictions on communication devices that are offered under the attributed patient engagement incentive policy are necessary to ensure that IOTA participants are not providing communication devices for purposes that are not aligned with the goals of the IOTA Model.

At § 512.458(d) of the proposed rule, we also proposed documentation requirements that pertain to the provision of attributed patient engagement incentives. The IOTA participant must maintain contemporaneous documentation of items and services furnished as attributed patient engagement incentives that includes, at minimum, the date an attributed patient engagement incentive is provided and the identity of the attributed patient to

[340] Szeifert, L., Molnar, M.Z., Ambrus, C., Koczy, A.B., Kovacs, A.Z., Vamos, E.P., Keszei, A., Mucsi, I., & Novak, M. (2010). Symptoms of depression in kidney transplant recipients: A cross-sectional study. American Journal of Kidney Diseases, 55(1), 132–140. *https://doi.org/10.1053/j.ajkd.2009.09.022*.

whom the item or service was provided. In accordance with the retrieval requirements for items that attributed patient engagement incentives, IOTA participants must document all retrieval attempts of items that are attributed patient engagement incentives, including the ultimate date of retrieval. IOTA participants must retain all records pertaining to the furnishing of attributed patient engagement incentives and make those records available to the Federal Government in accordance with section III.C.12. of this final rule.

Taken together, we believed the safeguards described in this section are necessary to ensure that attributed patient engagement incentives offered by an IOTA participant are provided in compliance with the intent of the proposed policy and, if met, the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect these attributed patient engagement incentives.

We considered not allowing IOTA participants to offer attributed patient engagement incentives for attributed patients in the IOTA Model, which would simplify the IOTA Model (89 FR 43518). Further, having no attributed patient engagement incentive policy would allow IOTA participants to direct available resources to the proposed Part B and Part D immunosuppressive drug cost sharing support policy described in section III.C.11.g(1) of this final rule. We took these considerations into account; however, we believed allowing for the maximum amount of flexibility possible for IOTA participants to meet the needs of attributed patients that relate to accessing a kidney transplant is consistent with the model's goals. In addition, we were unable to find any literature to suggest that one type of item or service, for example, cost sharing subsidies under Part B and Part D immunosuppressive drug cost sharing support, is of greater value to an individual waiting for a kidney transplant or having received a kidney transplant than another, for example, an attributed patient engagement incentive. We also considered including dental services as a service that may be offered as an attributed patient engagement incentive (89 FR 43518). Sources of oral infection must be resolved before an individual can receive a kidney transplant because post-transplant immunosuppression puts a kidney transplant recipient at greater risk for oral infections that can spread to the rest of the body.[341] We did not include dental services as an allowable attributed patient engagement incentive because we understand that sources of oral infection must be resolved before an individual can be waitlisted for a kidney transplant; in other words, prior to the ability of an individual to be attributed to the IOTA Model. We were interested in receiving comments on the extent to which dental issues emerge once an individual has been listed for a kidney transplant and whether we should consider dental services as an attributed patient engagement incentive under the auspices of the IOTA Model.

We solicited feedback on our proposal to allow IOTA participants to offer attributed patient engagement incentives in a manner that complies with the restrictions and safeguards in this section. We further solicited feedback on other barriers to remaining active on the kidney transplant waitlist, receiving organ offers, and adhering to pre- and post-transplant care that we may be able to address by expanding the attributed patient engagement incentives available to attributed patients through future rulemaking.

The following is a summary of the comments received on our proposed provisions for attributed patient engagement incentives, and our responses:

Comment: A few commenters expressed concern about the patient engagement incentives, as they would require significant planning and resources, and suggested that CMS should clarify whether coverage of dental services is included in the provision.

Response: We thank the commenters for their feedback. We understand the concerns about the potential burdens these incentives may place on IOTA participants. IOTA participants can choose whether to offer these patient engagement incentives. As such, if the logistical challenges and financial burden for IOTA participants exceeds the benefits for the IOTA participants, then the benefit does not need to be provided. Our goal is to ensure that beneficiary incentives effectively support patient care without imposing unnecessary burdens on IOTA participants.

We considered but did not ultimately include dental services as an allowable attributed patient engagement incentive because sources of oral infection must be resolved before an individual can be waitlisted for a kidney transplant; in other words, prior to the ability of an individual to be attributed to the IOTA Model.

We are finalizing this policy as proposed. However, we appreciate these insights and will take them into account in future rulemaking cycles.

Comment: Several commenters suggested the provision should also address health-related social needs (HRSNs) for patients on the waitlist and provide full living donor cost reimbursement including costs not covered by other payers, include mechanisms to help offset the cost of providing these incentives, and provide more flexibility.

Response: We thank the commenters for their suggestion. As described and finalized in § 512.446(a) of this final rule, IOTA participants may voluntarily submit a health equity for all PYs of the IOTA Model. We direct readers to section III.C.8.c of this final rule for further discussion on health equity plans in the IOTA Model. We believe that these health equity plans address HRSNs for patients on the waitlist. If in the future CMS requires the collection of HRSN data from Medicare provider and suppliers more widely and strengthens the availability of HRSN data, we will consider if there is sufficient and high-quality HRSN data available in future baseline years as we consider potential future changes to the model design.

Regarding living donor cost reimbursement, we note that Medicare or the kidney recipient's private insurance will generally cover the medical costs of testing and surgery for a living kidney donor. We understand, however, that there are often costs that are not reimbursed, such as meals, lodging, and transportation costs. As discussed later in this section, we are not issuing any fraud and abuse waivers in this final rule. A model provision protecting such reimbursement could be susceptible to abuse by potentially impermissibly steering beneficiaries in their selection of kidney transplant hospitals so as to mitigate costs for their donors, disadvantaging smaller kidney transplant hospitals without resources to provide this remuneration, and incentivizing donation decisions.

Comment: Several commenters suggested that CMS change the attributed patient engagement incentives to include additional services such as Medical Nutrition Therapy, dental coverage, and home phlebotomy and infusion services.

Response: We thank the commenters for their suggestion. The suggested expansion of Medical Nutrition

[341] Kwak, E.J., Kim, D.J., Choi, Y., Joo, D.J., & Park, W. (2020). Importance of oral health and dental treatment in organ transplant recipients. International Dental Journal, 70(6), 477–481. *https://doi.org/10.1111/idj.12585.*

Therapy, home phlebotomy and infusion services was not included in the proposed rule, and we therefore are not finalizing these expansions suggested by the commenters in this final rule. We did not include dental services as an allowable attributed patient engagement incentive because we understand that sources of oral infection must be resolved before an individual can be waitlisted for a kidney transplant; in other words, prior to the ability of an individual to be attributed to the IOTA Model.

We are finalizing this policy as proposed with one exception. The reference to section III.C.g(2) for the Part B and Part D immunosuppressive drug cost sharing support was incorrect. We clarify that the Part B and Part D immunosuppressive drug cost sharing support is described in section III.C.11.g(1) of this final rule.

After consideration of the public comments received, we are finalizing our proposed provision for attributed patient engagement incentives, with a minor technical correction to update the section numbering in our regulation at § 512.458.

h. General Payment Waivers [342]

We stated in the proposed rule that we would need to waive certain Medicare program regulations in order to make the upside risk payments and downside risk payments discussed in the proposed rule and in sections III.C.6.c.(2)(a) and III.C.6.c.(2)(b) of this final rule, respectively.

Therefore, in accordance with the authority granted to the Secretary in section 1115A(d)(1) of the Act to waive certain requirements as may be necessary solely for purposes of testing models, and consistent with other mandatory models such as the ETC Model and the CJR Model, we proposed at 89 FR 43597 to waive requirements of section 1881(b) of the Act only to the extent necessary to make the upside risk payments and downside risk payments under the IOTA model. Section 1881(b) of the Act determines how Medicare FFS pays for services such as dialysis, transplantation, and home dialysis support services for individuals with ESRD. Waiving requirements of section 1881(b) of the Act is necessary for the upside risk payments and downside risk payments to be made to or collected from the IOTA Participants. These model payments will be made in addition to, and not in lieu of, the Medicare FFS payments provided under section 1881(b) of the Act.

We proposed to waive this requirement under section 1881(b) of the Act because these statutory provisions establish the current Medicare FFS payment methodology, which does not include the upside risk payments and downside risk payments. Without waiving these specific provisions of the Act to permit the upside risk payments and downside risk payments, we would not be able to implement and test whether the payment methodology of the model was effective at reducing program expenditures while preserving or enhancing the quality of care.

We also proposed at 89 FR 43597 to waive sections 1833(a) and 1833(b) of the Act to the extent necessary to make payments under the IOTA Model. The purpose of this proposed waiver was to ensure that the upside risk payments and downside risk payments, as described in sections III.C.6.c.(2)(a) and III.C.6.c.(2)(b), respectively, in this final rule, would not alter the beneficiary cost-sharing requirements for the related Part B services received by IOTA participants. We did not propose to alter the existing Medicare beneficiary cost sharing structure, and this waiver would maintain that existing structure while enabling the upside risk payments and downside risk payments under the IOTA model.

Therefore, we proposed to waive the requirements of sections 1881(b), 1833(a), and 1833(b) of the Act to the extent necessary to make the payments we proposed under the IOTA Model (89 FR 43597). We sought comment on our proposed waivers of Medicare payment requirements related to the upside risk payment and downside risk payment and beneficiary cost sharing.

We received no public comments on these proposed waivers. As such, we are finalizing our proposal to waive sections 1881(b), 1833(a) and 1833(b) of the Act only to the extent necessary to make payments under the IOTA Model at § 512.470 without modification.

i. Fraud and Abuse Waiver and OIG Safe Harbor Authority

Under section 1115A(d)(1) of the Act, the Secretary may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii) of the Act, and certain provisions of section 1934 of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act.

For this model and consistent with the authority under section 1115A(d)(1) of the Act, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act. No fraud or abuse waivers are being issued in this document; fraud and abuse waivers, if any, would be set forth in separately issued documentation. Any such waiver would apply solely to the IOTA Model and could differ in scope or design from waivers granted for other programs or models. Thus, notwithstanding any provision of this final rule, IOTA participants and IOTA collaborators must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued pursuant to section 1115A(d)(1) of the Act specifically for the IOTA Model.

In addition to or in lieu of a waiver of certain fraud and abuse provisions in sections 1128A and 1128B of the Act, at § 512.470 of the proposed rule, CMS proposed to waive sections 1881(b) and 1833(a) and 1833(b) of the Act only to the extent necessary to make certain payments under the IOTA Model. These waivers, while originally included in this section of the proposed rule, are general payment waivers and not fraud and abuse waivers. As such, this discussion has been moved to section III.C.11.h of this final rule.

CMS has made a determination, in this final rule, that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§ 1001.952(ii)(1) and (2)) is available to protect remuneration exchanged pursuant to certain financial arrangements and patient incentives that may be permitted under the final rule. Specifically, we determined that the CMS-sponsored models safe harbor would be available to protect the following financial arrangements and incentives: the IOTA Model Sharing Arrangement's gainsharing payments and alignment payments, the Distribution Arrangement's distribution payments, the Part B and Part D immunosuppressive drug cost sharing support policy and attributed patient engagement incentives.

We considered not allowing use of the safe harbor provisions (89 FR 43518). However, we determined that use of the safe harbor would encourage the goals of the model. We believed that a successful model requires integration

[342] Section III.C.11.h did not appear in the notice of proposed rulemaking, and the general payment waivers were instead discussed in section III.C.11.i, which also addressed fraud and abuse waivers and OIG safe harbor authority. This section III.C.11.h has been added here to address the general payment waivers separately, as they are distinct from the fraud and abuse waivers. As we stated in the proposed rule, the general payment waivers are necessary to make the upside risk payments and downside risk payments under the IOTA model. The proposed regulatory text regarding the general payment waivers at § 512.470 is not changed.

and coordination among IOTA participants and other health care providers and suppliers. We believed the use of the safe harbor would encourage and improve beneficiary experience of care and coordination of care among providers and suppliers. We also believed the safe harbor offers flexibility for innovation and customization. The safe harbor allows for emerging arrangements that reflect up-to-date understandings in medicine, science, and technology.

We sought comment on this proposal, including that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)) be available to IOTA participants and IOTA collaborators.

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

Comment: A few commenters expressed support for the fraud and abuse provision, stating that the IOTA participants needed protections in place to form financial arrangements necessary for the model.

Response: We thank the commenters for their support.

After consideration of the public comments received, we are finalizing our proposed provision for application of the CMS-sponsored model arrangements and patient incentives safe harbor at § 512.459.

12. Audit Rights and Record Retention

By virtue of their participation in an Innovation Center model, IOTA participants and IOTA collaborators may receive model-specific payments, access to Medicare payment waivers, or some other model-specific flexibility, such as the ability to provide cost sharing support to eligible attributed patients for the proposed Part B and Part D immunosuppressive drug cost sharing support policy. It is therefore necessary and appropriate for CMS to audit, inspect, investigate, and evaluate records and other materials related to participation in the IOTA Model. CMS must be able to audit, inspect, investigate, and evaluate records and materials related to participation in the IOTA Model to allow us to ensure that IOTA participants are in no way denying or limiting the coverage or provision of benefits for beneficiaries as part of their participation in the IOTA Model. We proposed to define ''model-specific payment'' to mean a payment made by CMS only to IOTA participants, or a payment adjustment made only to payments made to IOTA participants, under the terms of the IOTA Model that is not applicable to any other providers or suppliers; the term ''model-specific payment'' would include, unless otherwise specified, the model upside risk payment and downside risk payment, described in section III.C.6 of this final rule. It is necessary to propose this definition to distinguish payments and payment adjustments applicable to IOTA participants as part of their participation in the IOTA Model, from payments and payment adjustments applicable to IOTA participants as well as other providers and suppliers, as certain provisions of proposed part 512 would apply only to the former category of payments and payment adjustments.

There are audit and record retention requirements under the Medicare Shared Savings Program (see 42 CFR 425.314) and in other models being tested under section 1115A of the Act (see, for example, 42 CFR 510.110 and § 512.135).

We proposed to adopt audit and record retention requirements for the IOTA Model. Specifically, as a result of our proposal to revise the scope of the general provisions of 42 CFR part 512 Subpart A to include the IOTA Model, see proposed 42 CFR 512.100, we proposed to apply § 512.135(a) through (c) to each IOTA participant and its IOTA collaborators. In applying § 512.135(a) to the IOTA Model, the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, would have a right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of an Innovation Center model. In applying existing § 512.135(b) and (c) to the IOTA Model, an IOTA participant and its IOTA collaborators would be required to:

- Maintain and give the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, access to all documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the IOTA Model, including, without limitation, documents and other evidence regarding all of the following:

++ Compliance by the IOTA participant and its IOTA collaborators with the terms of the IOTA Model, including proposed new subpart A of proposed part 512.

++ The accuracy of model-specific payments made under the IOTA Model.

++ The IOTA participant's downside risk payments owed to CMS under the IOTA Model.

++ Quality measure information and the quality of services performed under the terms of the IOTA Model, including proposed new subpart A of proposed part 512.

++ Utilization of items and services furnished under the IOTA Model.

++ The ability of the IOTA participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

++ Where cost sharing support is furnished under the Part B and Part D immunosuppressive drug cost sharing support policy, the IOTA participant must maintain contemporaneous documentation that includes the identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided, the date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided, and the amount or amounts of Part B and Part D immunosuppressive drug cost sharing support that was provided.

++ Contemporaneous documentation of items and services furnished as attributed patient engagement incentives in accordance with § 512.458 that includes, at minimum, the date the attributed patient engagement incentive is provided and the identity of the attributed patient to whom the item or service was provided.

++ Patient safety.

++ Any other program integrity issues.

- Maintain the documents and other evidence for a period of 6 years from the last payment determination for the IOTA participant under the IOTA Model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the IOTA participant at least 30 days before the normal disposition date; or

++ There has been a termination, dispute, or allegation of fraud or similar fault against the IOTA participant or its IOTA collaborators, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

If CMS notifies the IOTA participant of a special need to retain a record or group of records at least 30 days before the normal disposition date, the IOTA participant would be required to maintain the records for such period of time determined by CMS. If CMS notifies the IOTA participant of a special need to retain records or there has been a termination, dispute, or

allegation of fraud or similar fault against the IOTA participant or its IOTA collaborators, the IOTA participant would be required to notify its IOTA collaborators of the need to retain records for the additional period specified by CMS. This provision would ensure that the government has access to the records.

We note that we previously adopted a rule at 42 CFR 512.110 defining the term ''days,'' as used in 42 CFR 512.135, to mean calendar days.

We solicited public comment on these proposals regarding audits and record retention.

The following is a summary of the comments received on our proposed provisions for auditing and record retention, and our responses:

Comment: CMS received a comment asking to use HIPAA documentation retention standards.

Response: We thank the commenter for this feedback. By applying § 512.135(a) through (c), CMS ensures that IOTA participants are in no way denying or limiting the coverage or provision of benefits for beneficiaries as part of their participation in the IOTA Model. We believe that the current document retention time is reasonable.

After consideration of the public comment we received, we are finalizing our proposal for Audit Rights and Record Retention as proposed at § 512.460. We are also finalizing without modification the proposed definition of model-specific payment at § 512.402.

13. Compliance and Monitoring

a. General

We proposed in § 512.462 of the proposed rule that CMS, or its approved designees, would conduct compliance monitoring activities, to ensure compliance by the IOTA participant and IOTA collaborators with the terms of the IOTA Model, including to understand IOTA participants' use of model-specific payments and to promote the safety of attributed patients and the integrity of the IOTA Model. Such monitoring activities would include, but not be limited to—

- Documentation requests sent to the IOTA participant and its IOTA collaborators, including surveys and questionnaires;
- Audits of claims data, quality measures, medical records, and other data from the IOTA participant and its IOTA collaborators;
- Interviews with the IOTA participant, including leadership personnel, medical staff, other associates, and its IOTA collaborators;
- Interviews with attributed patients and their caregivers;
- Site visits to the IOTA participant and its IOTA collaborators, which would be performed in accordance with § 512.462(c), described in section III.C.13.b of this final rule;
- Monitoring quality outcomes and attributed patient data;
- Tracking beneficiary complaints and appeals;
- Monitoring the definition of and justification for the subpopulation of the IOTA participant's eligible attributed patients that may receive Part B and Part D immunosuppressive drug cost sharing support in accordance with § 512.456; and
- Monitoring the provision of attributed patient engagement incentives provided in accordance with § 512.458.

Additionally, CMS is concerned about IOTA participants bypassing the match run, as defined in section III.C.5.d(1)(a) of this final rule, the rank order list of transplant candidates to be offered an organ. This practice, known as ''list diving,'' can improve efficiency in placing organs, but may undermine the mechanisms promoting fairness in rationing this scarce resource, if overused. We proposed that CMS would monitor out of sequence allocation of kidneys by assessing how often top-ranked attributed patients receive the organ that was offered to them and if they did not receive it, what the reason for that was.

We believe these specific monitoring activities, which align with those currently used in other models being tested by the Innovation Center, are necessary to ensure compliance with the terms of the IOTA Model and can protect attributed patients from potential harm that may result from the activities of the IOTA participant or its IOTA collaborators, such as attempts to reduce access to or the provision of medically necessary covered services.

We proposed at § 512.462 of the proposed rule that when CMS is conducting compliance monitoring and oversight activities, CMS or its designees would be authorized to use any relevant data or information, including without limitation Medicare claims submitted for items or services furnished to attributed patients who are Medicare beneficiaries. We believe that it is necessary to have all relevant information available to CMS during compliance monitoring and oversight activities, including any information already available to CMS through the Medicare program.

IOTA participants would remain subject to all existing requirements and conditions for Medicare participation as set out in Federal statutes and regulations and provider and supplier agreements, unless waived under the authority of section 1115A(d)(1) of the Act solely for purposes of testing the IOTA Model.

b. Site Visits

In § 512.462(c) of the proposed rule, we proposed that IOTA participants would be required to cooperate in periodic site visits conducted by CMS or its designee. Such site visits would be conducted to facilitate the model evaluation performed pursuant to section 1115A(b)(4) of the Act and to monitor compliance with the IOTA Model requirements. We further proposed that CMS or its designee would provide the IOTA participant with no less than 15 days advance notice of a site visit, to the extent practicable. Furthermore, we proposed that, to the extent practicable, CMS would attempt to accommodate a request that a site visit be conducted on a particular date, but that the IOTA participant would be prohibited from requesting a date that was more than 60 days after the date of the initial site visit notice from CMS. We believe the 60-day period would reasonably accommodate IOTA participant schedules while not interfering with the operation of the IOTA Model. Further, in § 512.462 of the proposed rule, we proposed to require the IOTA participant to ensure that personnel with the appropriate responsibilities and knowledge pertaining to the purpose of the site visit be available during any and all site visits. We believe this proposal is necessary to ensure an effective site visit and prevent the need for unnecessary follow-up site visits.

Further, we proposed in § 512.462 of the proposed rule that nothing in the previous sections would limit CMS from performing other site visits as allowed or required by applicable law. We believe that CMS must retain the ability to timely investigate concerns related to the health or safety of attributed patients or program integrity issues, and to perform functions required or authorized by law. In particular, we believe that it is necessary for CMS to monitor, and for IOTA participants to be compliant with our monitoring efforts, to ensure that they are not denying or limiting the coverage or provision of medically necessary covered services to attributed patients in an attempt to change model results or their model-specific payments, including discrimination in the provision of services to at-risk patients (for example,

due to eligibility for Medicare based on disability).

In the alternative, we considered allowing unannounced site visits for any reason. However, we determined that giving advanced notice for site visits for routine monitoring would allow the IOTA participant to ensure that the personnel with the applicable knowledge is available and would allow the IOTA participant the flexibility to arrange these site visits around their operations. However, we proposed in § 512.462 of the proposed rule that if there is a concern regarding issues that may pose risks to the health or safety of attributed patients or to the integrity of the IOTA Model, unannounced site visits would be warranted. We believe this would allow us to address any potential concerns in a timely manner without a delay that may increase those potential risks.

We direct readers to section III.C.13.c of this final rule for a summary of the comments received on our proposals regarding site visits and our responses.

c. Reopening of Payment Determinations

To protect the financial integrity of the IOTA Model, we proposed in § 512.462(d) that if CMS discovers that it has made or receives a request from the IOTA participant about an incorrect model payment, CMS may make payment to, or demand payment from, the IOTA participant.

CMS' interests include ensuring the integrity and sustainability of the IOTA Model and the underlying Medicare program, from both a financial and policy perspective, as well as protecting the rights and interests of Medicare beneficiaries. For these reasons, CMS or its designee needs the ability to monitor IOTA participants to assess compliance with model terms and with other applicable Medicare program laws and policies. We believe our monitoring efforts help ensure that IOTA participants are furnishing medically necessary covered services and are not falsifying data, increasing program costs, or taking other actions that compromise the integrity of the IOTA Model or are not in the best interests of the IOTA Model, the Medicare program, or Medicare beneficiaries.

We invited public comment on these proposed provisions regarding monitoring of the IOTA Model and alternatives considered.

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

Comment: A few commenters expressed support for the monitoring measures proposed to ensure that IOTA participants comply with the model requirements and the program is improving patient care.

Response: We thank the commenters for their support of this proposed policy.

Comment: A few commenters indicated concern that the compliance monitoring provision will negatively impact smaller transplant programs, cause interruptions in the quality and continuity of patient care and create significant administrative burdens.

Response: We understand the concerns facing smaller transplant programs; however, we disagree that the compliance monitoring provision will negatively impact smaller transplant programs. The IOTA Model's compliance monitoring activities align with those currently used in other models being tested by the Innovation Center as well as those any hospital would have under Medicare. Ensuring the integrity and sustainability of the IOTA Model as well as promoting the safety and protection of attributed patients is the purpose of the compliance monitoring provision regardless of the size of the transplant hospital.

Comment: We received a comment suggesting that the IOTA Model should establish a robust feedback mechanism that allows transplant hospitals and other stakeholders to provide ongoing input on the implementation and impact of the IOTA Model. The commenter believes that feedback would be crucial for adapting the model to real-world challenges and achieving its intended outcomes.

Response: We appreciate the comment and plan to have transparent and ongoing communications with all the participants as the model progresses to achieve the intended outcomes.

Comment: A commenter asked CMS to provide greater notice than 15 days prior to a site visit.

Response: We appreciate the commenters' feedback and support. As noted in the proposed rule, we believe that providing at least 15 days of notice before a site visit is sufficient. Furthermore, we proposed that, to the extent practicable, CMS would attempt to accommodate a request that a site visit be conducted on a particular date, but that the IOTA participant would be prohibited from requesting a date that was more than 60 days after the date of the initial site visit notice from CMS. We believe the 60-day period would reasonably accommodate IOTA participant schedules while not interfering with the operation of the IOTA Model.

After consideration of the public comment we received, we are finalizing the proposed monitoring practices, compliance with laws, site visits, and reopening of payments policies at § 512.462 with minor technical corrections to update cross references. Specifically, at § 512.462(d)(1) we are removing the cross reference to § 512.462 and replacing it to reflect § 405.986 of this chapter. At § 512.462(d)(1), we are also removing the cross reference to § 512.464 and replacing it to reflect § 405.902 of this chapter.

14. Evaluation

Section 1115A(b)(4) of the Act requires the Secretary to evaluate each model tested under the authority of section 1115A of the Act and to publicly report the evaluation results in a timely manner. The evaluation must include an analysis of the quality of care furnished under the model and the changes in program spending that occurred due to the model. Models tested by the Innovation Center are rigorously evaluated. For example, when evaluating models tested under section 1115A of the Act, we require the production of information that is representative of a wide and diverse group of model participants and includes data regarding potential unintended or undesirable effects. The Secretary must take the evaluation into account if making any determinations regarding the expansion of a model under section 1115A(c) of the Act. In addition to model evaluations, the Innovation Center regularly monitors model participants for compliance with model requirements.

For the reasons described in section III.C.13 of this final rule, these compliance monitoring activities are an important and necessary part of the model test. Therefore, we note that IOTA participants and their IOTA collaborators must comply with the requirements of 42 CFR 403.1110(b) (regarding the obligation of entities participating in the testing of a model under section 1115A of the Act to report information necessary to monitor and evaluate the model), and must otherwise cooperate with CMS' model evaluation and monitoring activities as may be necessary to enable CMS to evaluate the Innovation Center model in accordance with section 1115A(b)(4) of the Act. This participation in the evaluation may include, but is not limited to, responding to surveys and participating in focus groups. Subsequent to the publication of the proposed rule, we wish to clarify that the evaluation

activities may also include site visits and case studies.

We received no comments on the proposed evaluation approach and therefore are finalizing this provision without modification.

15. Learning

In the Specialty Care Models final rule (85 FR 61114), we established the voluntary ETC Learning Collaborative (ETCLC). The goals of the ETCLC are to increase the supply and use of deceased donor kidneys by convening OPOs, transplant hospitals, donor hospitals, and patients and families to reduce the variation in OPO and transplant hospital performance and reduce kidney non-use.[343] The ETCLC is addressing three national aims over a 5-year period: (1) achieve a 28 percent absolute increase in the number of deceased donor kidneys with a KDPI greater than or equal to 60 recovered for transplant from the 2021 OPTN/SRTR baseline of 11,284; (2) decrease the current national non-use rate of all procured kidneys with a KDPI ≥ 60 by 20 percent; and (3) decrease the current national discard rate of all procured kidneys with a KDPI < 60 by 4 percent. The ETCLC has developed Quality Improvement (QI) Teams that are identifying and implementing best practices based on the ETCLC Kidney Donation and Utilization Change Package. As of June 2023, 54 OPOs and 181 transplant hospitals were enrolled in ETCLC.[344]

While we considered continuing the ETCLC under the auspices of the IOTA Model in section III.C.15 of the proposed rule, we proposed to conclude the ETCLC at the end of the ETC Model test and implement a learning system specific to the IOTA Model. An IOTA Model learning system would deal only with issues specific to the IOTA Model and would have neither national aims nor include other providers in the transplant ecosystem such as OPOs or donor hospitals as regular participants. The advantages of this approach are that CMS could provide a forum for IOTA participants to discuss elements of the model, share experiences implementing IOTA Model provisions, and solicit support from peers in overcoming challenges that may arise. Since most transplant hospitals have less experience with Innovation Center models than other provider types, we believe an independent learning system would provide unique value to IOTA participants.

In section III.C.15 of the proposed rule, we also considered continuing ETCLC under the aegis of the IOTA Model. We believed many IOTA participants would already be enrolled in the ETCLC and dedicating staff and time to participating in QI Teams and engaging with the Kidney Donation and Utilization Change Package. We also believed that there may be overlap between the QI work being undertaken by ETCLC participants and the issues that would be of interest to IOTA participants. We further considered whether the ETCLC needed more time to achieve its national aims that could be provided by continuing the ETCLC under the IOTA Model.

We solicited feedback on our proposal to conclude the ETCLC with the ETC Model and implement a new learning system specific to the IOTA Model. We sought feedback on the following questions:

- What are specific examples of how ETCLC is supporting transplant hospital QI to increase access to kidney transplant?
- What features of a new learning system would be important for IOTA participants?
- Could the ETCLC meet IOTA participants' need for QI support to succeed in the model?

The following is a summary of the comments received on our proposed learning system for the IOTA Model, our proposal to end the ETCLC at the completion of the ETC Model, feedback on the questions we posed in the proposed rule at 89 FR 43600, and our responses:

Comment: A commenter was in favor of supporting the CMS proposal to develop an IOTA-specific learning system, instead of relying on the methods used by the ETCLC in the ETC Model. Additionally, a commenter supported finalizing the ETCLC with the ETC Model.

Response: We appreciate the feedback and support for a learning system specific to the IOTA Model. We agree it is important to provide specialized support due to the importance of the subject matter and due to prior limited interaction transplant programs may have had with other Innovation Center models or alternative payment models.

After consideration of the public comments we received, for the reasons set forth in this rule, we are finalizing a voluntary learning system focused on increasing kidney transplant access, as described in section III.C.15 of this final rule. This learning system will be independent of the ETCLC, which will conclude at the end of the ETC Model test. We intend for the learning system to support IOTA participants and IOTA collaborators throughout the model performance period. While we did not specifically include IOTA collaborators in the proposed rule, we believe it is important to allow IOTA collaborators to participate if they would like to due to their close relationship with and their contributions to IOTA participants and their performance.

Additionally, we note that we did not receive any public comments regarding the questions we sought feedback on in the proposed rule at 89 FR 43600.

16. Remedial Action and Termination

a. Remedial Action

At § 512.464 of the proposed rule, we proposed the Standard Provisions for Innovation Center Models relating to remedial actions, originally finalized as general provisions in the Code of Federal Regulations (42 CFR part 512 subpart A) that applied to specific Innovation Center models but that we proposed for expansion to all Innovation Center Models with model performance periods that begin on or after January 1, 2025, in section II.B. of this final rule would apply to the IOTA Model. We proposed that CMS could impose one or more remedial actions on the IOTA participant if CMS determines that—

- The IOTA participant has failed to furnish 11 or more transplants during the PY or any baseline years;
- The IOTA participant or its IOTA collaborator has failed to comply with any of the terms of the IOTA Model;
- The IOTA participant has failed to comply with transparency requirements as listed in section III.C.8.a. of this final rule;
- The IOTA participant or its IOTA collaborator has failed to comply with any applicable Medicare program requirement, rule, or regulation;
- The IOTA participant or its IOTA collaborator has taken any action that threatens the health or safety of an attributed patient;
- The IOTA participant or its IOTA collaborator has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model;
- The IOTA participant or its IOTA collaborator has undergone a change in control, as described in section III.C.17.b of this final rule, that presents a program integrity risk;
- The IOTA participant or its IOTA collaborator is subject to any sanctions

[343] *End Stage Renal Disease Treatment Choices Learning Collaborative—End Stage Renal Disease Treatment Choices Learning Collaborative—QualityNet Confluence.* (n.d.). Qnetconfluence.cms.gov. Retrieved May 30, 2023, from *https://qnetconfluence.cms.gov/display/ETCLC/End+Stage+Renal+Disease+Treatment+Choices+Learning+Collaborative.*

[344] Ibid.

of an accrediting organization or a Federal, State, or local government agency;

- The IOTA participant or its IOTA collaborator is subject to investigation or action by HHS (including the HHS–OIG or CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint or filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action;
- The IOTA participant or its IOTA collaborator has failed to demonstrate improved performance following any remedial action imposed by CMS; or
- The IOTA participant has misused or disclosed beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

At § 512.464 of the proposed rule, we proposed that CMS may take one or more of the following remedial actions if CMS determines that one or more of the grounds for remedial action described in section III.C.16.a. of this final rule has taken place:

- Notify the IOTA participant and, if appropriate, require the IOTA participant to notify its IOTA collaborators of the violation;
- Require the IOTA participant to provide additional information to CMS or its designees;
- Subject the IOTA participant to additional monitoring, auditing, or both;
- Prohibit the IOTA participant from distributing model-specific payments, as applicable;
- Require the IOTA participant to terminate, immediately or by a deadline specified by CMS, its sharing arrangement with an IOTA collaborator with respect to the IOTA Model;
- Terminate the IOTA participant from the IOTA Model;
- Suspend or terminate the ability of the IOTA participant to provide Part B and Part D immunosuppressive drug cost sharing support, or attributed patient engagement incentives in accordance with sections III.C.11.g(1) and (2) of this final rule.
- Require the IOTA participant to submit a corrective action plan (CAP) in a form and manner and by a deadline specified by CMS;
- Discontinue the provision of data sharing and reports to the IOTA participant;
- Recoup model-specific payments;
- Reduce or eliminate a model-specific payment otherwise owed to the IOTA participant, as applicable; or
- Such other action as may be permitted under the terms of the IOTA Model.

As part of the Innovation Center's monitoring and assessment of the impact of models tested under the authority of section 1115A of the Act, CMS has a special interest in ensuring that these model tests do not interfere with the program integrity interests of the Medicare program. For this reason, CMS monitors actions of IOTA participants for compliance with model terms, as well as other Medicare program rules. When CMS becomes aware of noncompliance with these requirements, it is necessary for CMS to have the ability to impose certain administrative remedial actions on a noncompliant model participant.

In the alternative, we considered a policy where the IOTA participant would remain in the IOTA Model regardless of any noncompliance. However, if there are circumstances in which the IOTA participant has engaged, or is engaged in, egregious actions, we proposed that CMS may terminate the IOTA participant, as further described in section III.C.16.b. of this final rule. In addition, we considered allowing IOTA participants access to their data and reports regardless of their compliance with the requirements of the IOTA Model, however, we proposed to discontinue data sharing and reports as a potential remedial action if there are grounds for doing so.

We sought comment on these proposed provisions regarding the proposed grounds for remedial actions, remedial actions generally, and whether additional types of remedial action would be appropriate.

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

Comment: A few commenters expressed support for the IOTA Model grounds for remedial action and types of remedial action.

Response: We thank commenters for their feedback and support.

Comment: A commenter suggested that modest penalties for opting out of the IOTA Model could be bypassed in an economically rational way and ultimately threaten efforts to accurately assess the model.

Response: Participation in the IOTA Model is mandatory, so a participant cannot opt out. If a participant does not comply with the participation requirements of the IOTA Model, there will be remedial actions, which could include reducing or eliminating model specific payments or discontinuing data sharing and reports.

Comment: A commenter suggested that CMS should remove the risk that a program failing to meet the HEP requirements are subject to remedial action.

Response: We are no longer requiring health equity plans so participants will not be subject to remedial action for not submitting a plan.

After consideration of the public comments, for the reasons set forth in this final rule, we are finalizing our proposal on remedial actions as proposed at § 512.464 with a slight modification to update language to accurately reflect what we proposed at 89 FR 43618. Specifically, we are modifying the regulatory text at § 512.464(a)(1) to specify that CMS may impose remedial actions if CMS determines that the IOTA participant has failed to furnish 11 or more kidney transplants for patients aged 18 years or older, regardless of payer, during a PY or any baseline years.

b. Termination of IOTA participant From the IOTA Model by CMS

At proposed § 512.466(a), we proposed that CMS may immediately or with advance notice terminate an IOTA participant from participation in the IOTA Model if:

- CMS determines that it no longer has the funds to support the IOTA Model;
- CMS modifies or terminates the model pursuant to section 1115A(b)(3)(B) of the Act;
- CMS determines that the IOTA participant—

++ Has failed to comply with any model requirement or any other Medicare program requirement, rule, or regulation;

++ Has failed to comply with a monitoring or auditing plan or both;

++ Has failed to submit, obtain approval for, implement or fully comply with the terms of a CAP;

++Has failed to demonstrate improved performance following any remedial action;

++ Has taken any action that threatens the health or safety of a Medicare beneficiary or other patient;

++Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model;

++ Has undergone a change in control; [345] or

[345] At § 512.468(b)(2), we proposed that CMS may terminate an IOTA participant from the IOTA Model if the IOTA participant undergoes a change

++ Assigns or purports to assign any of the rights or obligations under the model, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.

• Poses significant program integrity risks, including but not limited to:

++ Is subject to sanctions or other actions of an accrediting organization or a Federal, State, or local government agency; or

++ Is subject to investigation or action by HHS (including OIG or CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

We requested comment and feedback on the proposal for termination of an IOTA participant from participating in the IOTA Model.

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

Comment: A few commenters expressed concern that the termination provision may allow transplant programs not interested in the model to simply accept a fine and exit the model and offers no downside to enrolled participants.

Response: Participation in the IOTA Model is mandatory, so a participant cannot exit the model. There are downside consequences if a participant does not comply with the requirements of the IOTA Model, such as remedial actions, which could include reducing or eliminating model specific payments or discontinuing data sharing and reports. The participant would not be able to accept a fine and exit the model, but rather negative financial consequences would be imposed, and continue to be imposed in subsequent Performance Years, on the participant. The participant would also be required to continue its participation in the IOTA Model.

After considering public comments, for the reasons set forth in this rule, we are finalizing our policy for termination of an IOTA participant from the IOTA Model by CMS as proposed in our regulation at § 512.466(a), with slight modifications. Specifically, we are redesignating what was proposed at § 512.466(a)(3)(vii) to be § 512.466(a)(3)(viii). We are also redesignating what was proposed at § 512.466(a)(3)(viii) to be § 512.466(a)(3)(ix). Lastly, at § 512.468(b)(2), we proposed that CMS may terminate an IOTA participant from the IOTA Model if the IOTA participant undergoes a change of control. As such, we have added a corresponding provision at § 512.466(a)(3)(vii), which allows for termination for a change in control consistent with § 512.468(b)(2).

c. Termination of Model Participation by IOTA Participant

Given the mandatory nature of this model, we proposed at § 512.466(b) of the proposed rule that an IOTA participant would not be able to terminate its own participation in the model. Maintaining a cohort of participants as close to 50 percent of eligible kidney transplant hospitals across the country is critical to evaluation of the IOTA Model. As such, while we proposed CMS may terminate an IOTA participant for reasons such as failure to meet eligibility criteria or change in kidney transplant hospital status, as described in section III.C.16.b. of this final rule, we did not propose voluntary termination by the IOTA participant.

We considered allowing an IOTA participant to voluntarily terminate their participation in the model; however, we felt this went against the mandatory nature of the model and jeopardized our ability to evaluate model success and savings.

We solicited comment and feedback on our proposal not to allow IOTA participants to terminate their participation in the IOTA Model.

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

Comment: A commenter shared their support for not allowing participants to terminate themselves from the model.

Response: We appreciate your feedback and support.

After considering public comments, we are finalizing our policy for termination of model participation by IOTA participant as proposed in our regulation at § 512.466(b).

d. Financial Settlement Upon Termination

In section III.C.16.d of the proposed rule, we proposed that if CMS terminates the IOTA participant's participation in the IOTA Model or CMS terminates the IOTA Model, CMS would calculate the final performance score and any upside risk payment or downside risk payment, if applicable, for the entire PY in which the IOTA participant's participation in the model or the IOTA Model was terminated.

We proposed that if CMS terminates an IOTA participant for any reason listed in section III.C.16.b of this final rule, CMS shall not make any payments of upside risk payment for the PY in which the IOTA participant was terminated, and the IOTA participant shall remain liable for payment of any downside risk payment up to and including the PY in which termination becomes effective (89 FR 43602). We proposed that CMS would determine the IOTA participant's effective date of termination.

We considered that in the event of termination, CMS would not pay any upside risk payments for the year in which the IOTA participant was terminated, but also only keep the IOTA participant liable for paying CMS any downside risk payments for completed PYs and not the year in which the IOTA participant is terminated (89 FR 43602). However, to deter poor or non-compliant performance, we believe it necessary to also keep the IOTA participant liable for paying to CMS any downside risk payment for the PY in which the IOTA participant is terminated.

We solicited comment on this proposal and alternative considered.

We received no comments on our proposed financial settlement upon termination policies and therefore are finalizing these proposals at § 512.466(c) without modification.

e. Termination of the IOTA Model

In the proposed rule, we proposed that the general provisions relating to termination of the model by CMS in 42 CFR 512.165 would apply to the IOTA Model (89 FR 43602). Consistent with these provisions, in the event we terminate the IOTA Model, we would provide written notice to IOTA participants specifying the grounds for termination and the effective date of such termination. As provided by section 1115A(d)(2) of the Act and *§ 512.170(e),* termination of the model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review. We proposed that in the event of termination of the model, financial settlement terms would be the same as those set forth in section III.C.16.d. of this final rule.

We solicited public comment on these proposals regarding termination of the IOTA Model.

We received no comments on the proposed policies for termination of the IOTA Model, and therefore are finalizing these proposals with slight modification at § 512.466(d) to clarify

of control. For consistency, in this final rule, we have added a corresponding provision at § 512.466(a)(3)(vii).

that, as stated in this section and in the proposed rule at 89 FR 43602, termination of the IOTA Model under section 1115A(b)(3)(B) of the Act is not subject to administrative or judicial review.

17. Miscellaneous Provisions on Bankruptcy and Other Notifications

a. Notice of Bankruptcy

In the proposed rule, we proposed that if an IOTA participant has filed a bankruptcy petition, whether voluntary or involuntary, the IOTA participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the IOTA participant under the terms of each model tested under section 1115A of the Act in which the IOTA participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved (89 FR 43602). We proposed the notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the IOTA participant is participating or has participated. This list would not need to identify a model tested under section 1115A of the Act in which the IOTA participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the IOTA participant and CMS have been fully and finally resolved with respect to that model. The notice to CMS would be addressed to the CMS Office of Financial Management, Mailstop C3–01–24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified on the CMS website for purposes of receiving such notices.

We received no comments on these proposals and therefore are finalizing these provisions at § 512.468(a), without modification.

b. Change in Control

We proposed that CMS could terminate an IOTA participant from the model if the IOTA participant undergoes a change in control. We proposed that the IOTA participant shall provide written notice to CMS at least 90 days before the effective date of any change in control. For purposes of this rule, we proposed a ''change in control'' would mean at least one of the following: (1) the acquisition by any ''person'' (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the IOTA participant representing more than 50 percent of the IOTA participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the IOTA participant by any individual or entity; (3) any merger, division, dissolution, or expansion of the IOTA participant (4) the sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the IOTA participant; or (5) the approval and completion of a plan of liquidation of the IOTA participant, or an agreement for the sale or liquidation of the IOTA participant.

We received no comments on these proposals and therefore are finalizing these provisions at § 512.468(b) as proposed, with a slight modification to include a cross-reference to § 512.466 at § 512.468(b)(2). We are also finalizing without modification the proposed definition of change in control at § 512.402.

c. Prohibition on Assignment

We proposed that except with the prior written consent of CMS, an IOTA participant shall not transfer, including by merger (whether the IOTA participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise: (1) any discretion granted it under the model; (2) any right that it has to satisfy a condition under the model; (3) any remedy that it has under the model; or (4) any obligation imposed on it under the model. We proposed that the IOTA participant provide CMS 90 days advance written notice of any such proposed transfer. We proposed this obligation remains in effect after the expiration or termination of the model or the IOTA participant's participation in the model and until final payment by the IOTA participant under the model has been made. We proposed CMS may condition its consent to such transfer on full or partial reconciliation of upside risk payments and downside risk payments. We proposed that any purported transfer in violation of this requirement is voidable at the discretion of CMS.

We received no comments on these proposals and therefore we are finalizing these provisions, as proposed without modification, at § 512.468(c).

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

In the proposed rule (89 FR 43603), we sought input on several requests for information (RFIs).

1. Patient-Reported Outcome Performance Measures (PRO–PM)

In the proposed rule (89 FR 43603), we sought comment on the potential use of patient-reported outcome performance measures in the IOTA Model. Specifically, we sought feedback on the following questions:

- For a meaningful evaluation of transplant program outcomes from the recipient point of view, are there currently any validated PROMs of quality of life that are appropriate for use in the IOTA Model?
- Are there specific aspects of quality of life (QOL) that are particularly important to include for these populations? Why are these aspect(s) of QOL a high priority for inclusion in a survey? What should these metrics be (that is, measurement tools, instruments, concepts)? How should they be measured?
- For kidney transplant recipients: What other topic area(s) should be included in a new patient-reported outcome measure or performance measure assessing quality of life?
- For kidney transplant recipients: What domains of HRQOL can be influenced or improved by actions taken by transplant hospital and thus may be appropriate for performance measurement?

In addition, we sought input on the questions later in this section on existing PROMs and quality measures that are currently being used by transplant hospitals.

- Which patient-reported outcomes measure(s) that assess quality of life in kidney transplant recipients are currently being used?

++ What information is collected in these PROMs? How well do these surveys perform? What are the strengths of the survey(s) currently in use?

++ What content area(s) are missing from these survey(s) that are currently in use?

++ Which content area(s) are low priority or not useful in these currently used survey(s)? Why are they not useful?

++ How are the results and findings of these current survey(s) used to evaluate and improve quality of life/care? Are the results and findings of these current survey(s) used for other purposes?

• Are there any other PROMs or PRO–PMs that CMS should consider using to measure a transplant program's performance?
• Are there any other quality measures in general that CMS should consider using to measure a transplant program's performance?
• For transplant hospitals: Can PROs be effectively used to assess performance?
• For transplant hospitals: Does a reporting requirement effectively incentivize a transplant hospital to improve patient quality of life without tying payment to performance?
• When is the appropriate time to measure HRQOL post-transplantation?
• For transplant hospitals: What, if any, challenge(s) are there to collecting information about patient quality of life?
• For kidney transplant recipients: What, if any, challenge(s) are there to reporting information about patient quality of life?
• For transplant hospitals: What actions or approaches by transplant hospitals would facilitate the collection of quality-of-life information?
++ What data collection approach(es) would be most likely to promote participation by transplant recipients to a survey (for example, web-based, paper-and-pencil, etc.)?
++ How much time would transplant hospitals need to build processes to collect and use data in a meaningful way?
• For transplant hospitals: How could CMS support transplant hospitals in introducing a measure like this into the model?

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

2. Access to Waitlist Measure

In the proposed rule (89 FR 43604), we sought comment on the potential use of an access to waitlist measure in the IOTA Model. Specifically, we sought feedback on the following questions:
• For kidney transplant hospitals: What existing measures are currently being used to measure access to the waitlist?
++ What are the strengths and weaknesses of those measures?
++ What are the domains of those measures?
• For kidney transplant recipients and dialysis and ESRD patients: Why is a quality measure that looks at access to waitlist important to include?
• When measuring access to waitlist, what components should be analyzed (for example, time from referral to waitlist, time from waitlist to transplant)?
• What data would be necessary to create a measure on those specified components? How could that data be transmitted to CMS that minimizes additional burden to transplant hospitals?
• What data would be necessary to create a measure of time to referral to waitlist, time from referral to waitlist and time from waitlist to transplant? How could that data be transmitted to CMS that reduces burden to transplant hospitals?

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

3. Interoperability

In the proposed rule (89 FR 43605), we sought comment on interoperability requirements in the IOTA Model. Specifically, we sought comment on how CMS can promote interoperability in the proposed IOTA Model; in particular, we sought comment on the extent to which participants are planning on participating in the Trusted Exchange Framework and Common Agreement (TEFCA) in the next 1–2 years, as well as other means by which interoperability may support care coordination in the IOTA Model. We noted that any further proposals related to interoperability in the IOTA Model would be proposed through future notice and comment rulemaking.

We received no comments on this RFI.

IV. Collection of Information Requirements

The Standard Provisions for Innovation Center Models and the Increasing Organ Transplant Access (IOTA) Model would be 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 be reviewed by the Office of Management and Budget.

V. Regulatory Impact Analysis

A. Statement of Need

The best treatment for most patients with kidney failure is transplantation. Kidney transplants provide improved survival and quality of life relative to dialysis and generates savings to the Medicare Trust Fund over 10 years, but only 30 percent of patients with end-stage renal disease (ESRD) are living with one.[346] The underutilization of kidney transplantation is particularly prominent among structurally disadvantaged populations. The kidney transplant process involves silos of care, gaps in accountability, disparities, and misaligned financial incentives that we believe value-based care incentives are well positioned to target.[347]

The IOTA Model will be a mandatory payment model, beginning on July 1, 2025, and ending June 30, 2031, that tests whether upside and downside performance-based payments (''upside risk payments'' and ''downside risk payments'') increase the number of kidney transplants performed by select IOTA participants (that is, transplant hospitals). Performance would be measured across three domains: (1) Achievement; (2) Efficiency; and (3) Quality. The achievement domain would assess each selected IOTA participant on the overall number of kidney transplants performed relative to a participant-specific target. The efficiency domain would assess the kidney organ offer acceptance rates of each selected IOTA participant relative to a national rate. The quality domain would assess the quality of care provided by the selected IOTA participant based on the composite graft survival rate. Each selected IOTA participant's performance score across these three domains would determine the amount of the performance-based payment that CMS would pay to the selected IOTA participant, or that the selected IOTA participant would pay to CMS. The upside risk payment would be a lump sum payment paid by CMS to the selected IOTA participants with

[346] Organ Procurement and Transplantation Network. Kidney Donor Profile Index (KDPI) Guide for Clinicians. *https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians/;* United States Renal Data System. 2022. USRDS Annual Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 9: Healthcare Expenditures for Persons with ESRD. Figure 9.11.

[347] 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.*

high final performance scores. Conversely, the downside risk payment would be a lump sum payment paid to CMS by the selected IOTA participants with low final performance scores.

1. Analytic Baseline

Historical data for the analytic baseline are from the Organ Procurement and Transplant Network/Scientific Registry of Transplant Recipients (OPTN/SRTR).[348] There were 24,667 total adult kidney transplants in the United States in 2021, with a growth rate of 7.3 percent from 2020 to 2021. Similarly, the 5-year compound annual growth rate (CAGR) for the pre-pandemic years of 2015–2019 was 7.1 percent. The majority, 86.7 percent, of adult kidney transplants were from deceased donors in 2021. The trend in growth for deceased donor kidney transplants has been steadily increasing since the revision of the kidney allocation system in 2014, while the trend in growth for living donor kidney transplants has been relatively stable. The number of adult deceased donor kidney transplants increased 5.7 percent from 2020 to 2021, a slowdown from the 2015–2019 CAGR of 7.8 percent.

Among the 18,931 adult deceased donor kidney transplant recipients in 2021, 64.7 percent reported Medicare as their primary payer (stable from 64.8 percent in 2020) and 24.0 percent reported private insurance as their primary payer (down from 25.7 percent in 2020). Deceased donor kidney transplant recipients had 2015–2019 CAGR of 6.9 percent for Medicare as their primary payer and 11.6 percent for private insurance as their primary payer. The age distribution of the 18,931 adult deceased donor kidney transplant recipients in 2021 showed that the majority of recipients are younger than the aged Medicare population. Specifically, 11.5 percent of recipients were ages 18–34 years, 26.1 percent were ages 35–49 years, 40.5 percent were ages 50–64 years, and 21.9 percent were at least 65 years of age at the time of transplant. The 2015–2019 CAGR was greatest for the two latter age categories, at 9.3 percent and 14.4 percent for ages 50–64 years and 65+ years, respectively.

The supply of donated kidneys has not grown with the demand from kidney transplant recipient candidates. There were a total of 96,130 adult kidney transplant candidates on the transplant waitlist at the end of the year in 2021, which included 41,765 newly added candidates. The number of newly added adult candidates to the waitlist increased 11.7 percent from 2020 to 2021, recovering from the pandemic-related decline in the prior year, and exceeding the 2015 to 2019 CAGR of 9.2 percent.

For the model, we assumed an average of $40,000 in savings to Medicare over a 10-year period for each additional kidney transplant furnished to a Medicare beneficiary compared to remaining on dialysis. For the 50 percent of IOTA participants proposed to be randomly selected to participate in the model, we assume that the total number of kidney transplants from all payers over the 6-year model performance period would have a CAGR of 6.6 percent in the absence of the model (for example, if the rule is not finalized). We also assume that the 6-year model performance period CAGR for the total number of kidney transplants furnished to beneficiaries with Medicare as the primary payer would be 7.0 percent. The baseline share of deceased donor kidneys that are currently discarded is roughly 20 percent. If the IOTA Model were not implemented, then IOTA participants would not have the performance-based upside and downside risk payments to increase their organ offer acceptance rate. Therefore, pre-pandemic growth rates for deceased donor kidney transplants would be expected to continue during the projection period. The living donor kidney transplant growth rate is also expected to continue close to pre-pandemic rates in the absence of the model.

One initiative and one recent reform have the potential to impact the IOTA study population, even in the absence of the model. First, the OPTN Modernization Initiative that HRSA announced in March 2023 includes several actions to strengthen accountability, transparency, equity, and performance in the OPTN.[349] Some of the proposed OPTN Modernization Initiative actions that are relevant to the IOTA Model's target population include data dashboards detailing individual transplant center and organ procurement organization data on organ retrieval, waitlist outcomes, and transplants, and demographic data on organ donation and transplant will be made available to patients. In the absence of the IOTA Model, the OPTN Modernization Initiative has the potential to incentivize IOTA participants to improve upon some of the IOTA Model's incentive domains, such as improving the organ offer acceptance rate and post-transplant outcomes.

Second, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act (H.R. 5534; also known as the Immuno Bill) passed in November 2020, which stipulates lifelong coverage for immunosuppressive drugs for kidney transplant recipients, has the potential to improve patient survival.[350] Beginning January 1, 2023, the Medicare Part B Immunosuppressive Drug benefit covers immunosuppressive drugs beyond 36 months for eligible kidney transplant recipients that do not have other health coverage for immunosuppressive drugs. The most current statistics of post-transplant patient survival are reported by Hariharan et al.[351] The authors used data from the OPTN/SRTR and found that post-deceased donor kidney transplant patient survival rates at years 1 and 3 are 97.1 percent and 93.3 percent, respectively, for transplantation taking place during 2016–2019. Post-living donor kidney transplant patient survival rates are 99.1 percent and 96.5 percent during the same period. These rates decrease over the longer term. For kidney transplantation during 2008–2011, patient survival rates at 10 years are 66.9 percent for deceased donor kidney transplants and 81.3 percent for living donor kidney transplants. The authors project that survival rates will continue to improve, explaining that the decline in survival starting 3 years after transplantation has been attributed to, and coincides with, the discontinuation of insurance coverage for long-term immunosuppressive medications.

B. Overall Impact

We have examined the impacts of this rule under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 titled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory

[348] Organ Procurement and Transplant Network/Scientific Registry of Transplant (OPTN/SRTR). ''OPTN/SRTR YYYY Annual Data Report: Kidney. Supplemental Data Tables.'' Where YYYY is for report years 2015, 2018, 2019, 2020, and 2021. *https://www.srtr.org/reports/optnsrtr-annual-data-report/.*

[349] HHS. 2023. ''HRSA Announces Organ Procurement and Transplantation Network Modernization Initiative.'' *https://www.hhs.gov/about/news/2023/03/22/hrsa-announces-organ-procurement-transplantation-network-modernization-initiative.html.*

[350] CMS. 2022. ''Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules. Final Rule.'' **Federal Register** 87 FR 66454: 66454–66511.

[351] Hariharan S, Irani AK, Danovitch G (2023). ''Long-Term Survival after Kidney Transplantation.'' *New England Journal of Medicine.* 385:729–43. *https://www.nejm.org/doi/full/10.1056/NEJMra2014530.*

Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 titled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), 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, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OMB's Office of Information and Regulatory Affairs (OIRA) in each case.

We have prepared a regulatory impact analysis (RIA) for major rules with significant regulatory action/s and/or that are significant under section 3(f)(1) of Executive order 12866 ($200 million or more in any 1 year). Based on our estimates from the CMS Office of the Actuary, OMB's OIRA has determined that this rulemaking is not significant per 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 Congressional Review Act), OMB's OIRA has also determined that this rule does not meet the criteria set forth in 5 U.S.C. 804(2). We solicited comment on the RIA and provide our responses to each comment later in the RIA.

C. Detailed Economic Analysis

Several important factors have been identified that lead to the discard of donated kidneys, including significant increased cost to hospitals for transplanting organs from older donors and/or donors with comorbidities. Value-based payments that reward hospitals for increasing the number of transplants as well as related quality and process measures may improve the acceptance of offered organs and outcomes for patients.[352] 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 SRTR dashboard.[353] Organ offer acceptance ratios [354] and the composite graft survival rate [355] 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 would receive upside or downside risk payments based on their performance across three domains: achievement, efficiency, and quality. The three domains would measure certain metrics and award points as shown in the following Table I:

TABLE I: IOTA PERFORMANCE DOMAINS

Domain	Metrics Description	Points
Achievement	The number of transplants performed relative to an IOTA participant-specific target. Rolling baseline.	60
Efficiency	Organ offer acceptance rate**,** which is a ratio of observed versus expected organ offer acceptances.	20
Quality	Composite graft survival rate.	20
Total Possible		100

The upside risk payment would be a lump sum payment paid by CMS to the IOTA participants that achieve high final performance scores. Conversely, the downside risk payment would be a lump sum payment paid to CMS by the IOTA participants with low final performance scores. The performance-based payments would be based on the following thresholds. Total scores of 60 and above would result in a maximum upside risk payment of $15,000, as shown in equation 7. Scores below 60 would fall into the neutral zone with no upside or downside risk payment in PY 1. After the first PY, scores from 41 to 59 would 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 would be $2,000, as shown in equation 8. This performance-based payment would then be multiplied by the total number of kidney transplants furnished by the IOTA participant to attributed patients for which model payments apply during the PY.

Equation 7: IOTA Upside Risk Payment for Scores of 60 and Above

[352] Cooper, M. et. al. (2018). Report of the National Kidney Foundation Consensus Conference to Decrease Kidney Discards. *Journal of Clinical Transplantation and Translational Research, https://doi.org/10.1111/ctr.13419.*

[353] 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.

[354] 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.

[355] 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-specific-reports/.* Accessed May 25, 2023.

$$IOTA\ Lump\ Sum\ Payment = \$15{,}000 * \left(\frac{Final\ Performance\ Score - 60}{40}\right) * Medicare\ Kidney\ Transplants$$

Equation 8: IOTA Downside Risk Payment for Scores of 40 and Below

$$IOTA\ Performance\ Payment = \$2{,}000 * \left(\frac{40 - Final\ Performance\ Score}{40}\right) * Medicare\ Kidney\ Tranplants$$

We randomly selected half of all DSAs in the country and all eligible IOTA participants within those DSAs and applied assumptions for transplant growth and performance on other domains affecting the incentive formula 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.[356] [357] 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.

Comment: A few commenters provided justification for a revised payment methodology. A commenter recommended that CMS increase the maximum upside risk payment from $8,000 to $15,125 and the maximum downside risk payment from $2,000 to $3,750 and to apply these proposed payments for performance scores based on the national growth rate instead of to the IOTA participant's own past peak performance. The commenter expected that these modifications would likely yield significantly more savings. A few commenters additionally urged CMS to revise potential financial incentives for IOTA participants upward in congruence with the potential new savings assumption but did not offer any specific alternative payment amounts. A few commenters recommended that the transplant target should be based on the arithmetic mean of volume for the 3-year baseline period instead of the peak performance during the baseline period. The commenter stated that the proposed targets are likely to result in the imposition of significant penalties on high-performing participants.

Response: The maximum upside risk payment was increased from $8,000 in the proposed rule to $15,000 in the final rule (refer to section III.C.6. of this final rule (Payment) for the rationale behind the increase in the maximum risk payment amount). The maximum downside risk payment remained at $2,000. For clarification, in the proposed rule, the transplant target was equal to the highest number of deceased or living donor kidney transplants performed during the three-year baseline period trended forward by the national growth rate. In the final rule, the transplant target was updated to equal to the average number of transplants performed during baseline years trended forward by the national growth rate. Changing the transplant target to be the average of the baseline years instead of the highest number should set the base within reach for IOTA participants to achieve their targets.

For IOTA participants randomized into the model, assumptions were also made for gradual improvement over baseline kidney acceptance rates, with individual IOTA participants assumed to have, in year 1, up to a 10-percent chance (up to a 20-percent chance by year 2, etc.) of increasing their acceptance ratio by between 20 to 80 percentage points and maintaining such simulated improvement in ensuing model years. The share of IOTA participants receiving passing confidence intervals for the 1-year post transplant composite graft survival ratio was assumed to be roughly 95 percent in year 1, gradually improving by about half of a percentage point per year. Please see section III.C.5.e.(1). of this rule for the discussion on post-transplant outcomes.

Tables II, III, and IV show the possible point allocations for performance relative to target for the Achievement Domain, Efficiency Domain, and Quality Domain, respectively. For the Achievement Domain (Table II), the transplant target is the average number of transplants performed during baseline years trended forward by the national growth rate. For the Efficiency Domain (Table III), in recognition that all IOTA participants may not be able to achieve the highest national rank, but still may be performing beyond their previous standards, this domain will be scored in two ways: achievement scoring and improvement scoring (not displayed in Table III). IOTA participants will be awarded points based on the scoring system that yields the highest allocation. In Table III, organ-offer acceptance will be calculated as a rate ratio of observed organ offer acceptances versus expected organ offer acceptances. Performance will be assessed across all centers

[356] 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/.*

[357] 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.*

nationally. In the Quality Domain (Table IV), the composite graft survival rate is equal to the total number of functioning grafts divided by the total number of completed kidney transplants.

TABLE II: ACHIEVEMENT DOMAIN – SCORING FOR TRANSPLANT TARGET

Performance Relative to Target	Points Earned
≥ 125%	60
120% ≤ x < 125%	55
115% ≤ x < 120%	50
105% ≤ x < 115%	40
95% ≤ x < 105%	30
85% ≤ x < 95%	20
75% ≤ x < 85%	10
< 75%	0

TABLE III: EFFICIENCY DOMAIN - ACHIEVEMENT SCORING FOR ORGAN OFFER ACCEPTANCE RATE

Performance Relative to Target	Points Earned
≥ 80th Percentile	20
60th ≤ x < 80th Percentile	15
40th ≤ x < 60th Percentile	10
20th ≤ x < 40th Percentile	6
0 ≤ x < 20th Percentile	0

TABLE IV: QUALITY DOMAIN - SCORING FOR COMPOSITE GRAFT SURVIVAL RATE

Performance Relative to Target	Points Earned
≥ 80th Percentile	20
60th ≤ x < 80th Percentile	18
40th ≤ x < 60th Percentile	16
20th ≤ x < 40th Percentile	14
10th ≤ x < 20th Percentile	12
0 ≤ x < 10th Percentile	10

Table V later in this section shows the projected impacts for upside and downside risk payments, transplants, and Federal spending. Although transplant recipients with any type of insurance may benefit from a transplant hospital's participation in the model, model payments will be based on the number of transplant recipients who are beneficiaries with Medicare fee-for-service (FFS) coverage including beneficiaries enrolled in Medicare as a secondary payer. Just over one-third of IOTA participants are projected to receive upside risk payments in the first year, rising to about 43 percent over the succeeding 5 model years, with only a small fraction of participants projected to owe downside risk payments in any of years 2 through 6 (ranging from 16 to 18 percent). The magnitude of the average downside risk payment is relatively small, and the cumulative projected upside risk payments to IOTA participants, amounting to $117 million, are over 100 times the magnitude of a cumulative $1 million in projected receipts from downside risk payments from IOTA participants to CMS. The amount of projected savings from new transplants was greater than the net cost of payments in about 58 percent of simulation trials. The mean 3,683 added transplants over the 6-year model performance period is an increase from the proposed rule for the following reasons: (1) a more effective response in terms of added transplants was assumed in the final rule due to the larger maximum per-transplant incentive; and (2) more hospitals were estimated to receive a positive incentive any given year because the scoring thresholds were made more gradual and the surrounding quality scoring methodology would make higher scores more attainable. Overall, mean net savings totaled $28 million over 6 years, ranging from a savings of $152 million to a cost of $77 million at the 10th and 90th percentiles.

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

							6-Year Totals		
	7/1/25-6/30/26	7/1/26-6/30/27	7/1/27-6/30/28	7/1/28-6/30/29	7/1/29-6/30/30	7/1/30-6/30/31	Mean	10th Percentile	90th Percentile
Upside Risk Payments	$15	$17	$20	$21	$21	$23	$117	$90	$144
Downside Risk Payments	$0	$0	$0	$0	$0	$0	-$1	-$2	-$1
Total Net Payments	**$15**	**$17**	**$19**	**$21**	**$21**	**$23**	**$116**	**$89**	**$142**
Added Transplants	161	343	546	761	913	959	3,683	1,372	6,261
Impact on FFS Spending	**-$5**	**-$12**	**-$20**	**-$-29**	**-$37**	**-$40**	**-$144**	**-$152**	**-$37**
Mean Net Savings	**$9**	**$5**	**-$1**	**-$8**	**-$15**	**-$18**	**-$28**	**-$152**	**$77**

(Projected savings allocated to year of transplant; dollars in millions)

In Table V, 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 FFS spending from those transplants (because spending is reduced when transplants grow).

There is a wide range of potential changes in Federal spending for each new transplant. Savings on avoided dialysis may in many cases be exceeded when transplants are especially complex and post-transplant complications are more likely, for example when deceased organs have a high kidney donor profile index and/or recipients are of advanced age.[358] But even in such cases Federal savings can be substantial if Medicare is not primary payer at time of transplant or the beneficiary eventually returns to private insurance post-transplant. We relied on the savings per transplant estimate published in the ESRD Treatment Choices (ETC) Model final rule [359] to account for different primary payer scenarios at the time of transplant, as well as the likelihood that the beneficiary would have remained on Medicare after transplantation. For the ETC Model, OACT produced a 10-year savings to Medicare of approximately $32,000 per beneficiary for a deceased donor kidney transplant with a high-kidney donor profile index. For the proposed IOTA Model, we assumed the average Federal spending impact could range from a cautious $20,000 increase to optimistically at most a $100,000 savings per additional transplant (mean assumption being a $40,000 savings).

The mean assumption of $40,000 in savings is marginally higher than the ETC Model's 10-year estimated savings to Medicare of approximately $32,000 per beneficiary for a deceased donor kidney transplant with a high-kidney donor profile index because it includes at least some potential for an increase in other types of transplants. The 10-year estimated savings to Medicare of approximately $32,000 per beneficiary used in the ETC Model based on deceased donor, high-kidney donor profile transplants was assumed because of the relatively limited focus that model appeared to have on improving the number of transplants and outcomes for transplants. By comparison, the estimate for the IOTA Model still focused on deceased donor kidneys, but this model warranted a marginally higher savings per transplant estimate, allowing for the mean assumption of $40,000 in savings. To determine the outer bounds of the assumption, we identified individual points in our organ-type/payer matrix that ranged from a $100,000 increase in costs to $200,000 (or wider) in savings, so the bounds we chose for the estimate were based on realizing new transplants were going to be mixed across the matrix and not all congregated at an extreme end on one side or the other (keeping in mind that they will likely come mostly from decedent donor kidneys). We assumed that kidney transplant savings would accumulate in the year of the transplant even though the cost of the transplant would, in practice, lead to higher spending in the first year (unless Medicare was not the primary payer). It would likely take longer than the 6 model years for the cumulative net savings projected in Table III to ultimately materialize. The timing of when savings would accumulate could not be estimated with more precision for the following reasons. Savings could range from being virtually immediate if new transplants occur when a beneficiary is not Medicare primary payer status, to being backloaded if the beneficiary receives the transplant when Medicare is primary payer, to being a net cost if the beneficiary transplant fails within a short period after transplant. Given those uncertainties, and the underlying uncertainties about where the new transplants will materialize from (by donor and recipient), we were not able to imply more precision than we were able to model from the evidence.

Comment: Some commenters recommended that CMS increase the proposed estimate of $40,000 in savings to Medicare over a 10-year period for each additional kidney transplant furnished to a Medicare beneficiary compared to remaining on dialysis. The commenters expressed that the estimate understates Medicare savings resulting from kidney transplantation and a few commenters noted it is inconsistent with estimates calculated by commenters using United States Renal Data System (USRDS) data to compare costs for patients receiving a kidney transplant to those on dialysis. A few commenters cited published literature that also used USRDS data to support their concern that the savings to Medicare estimate may be in error. These commenters also noted that the published study used as an input for the savings assumption did not account for costs of death on the waiting list.

[358] Axelrod DA, Schnitzler MA, Xiao H, et al. 2018. ''An Economic Assessment of Contemporary Kidney Transplant Practice.'' *American Journal of Transplantation* 18: 1168–1176. *https://pubmed.ncbi.nlm.nih.gov/29451350/.*

[359] Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures, 85 FR 61335 (September 29, 2020) (codified at 45 CFR part 512, subpart A).

Response: In response to the commenters, we investigated the methodology and data sources in the Axelrod et al. (2018) study that was used as an input in our calculations. Ultimately, we decided to keep the proposed estimate of $40,000 in savings to Medicare over a 10-year period for each additional kidney transplant furnished to a Medicare beneficiary compared to remaining on dialysis. The key validity of the Axelrod et al. (2018) study is that the authors focused strictly on costs involving either—(1) maintenance dialysis as a service (that is, the payment to dialysis facilities for regular maintenance dialysis); or (2) kidney transplant surgery (including related costs before and after transplant surgery) as reported on hospital cost reports and potential downstream costs related to graft failure and return to dialysis. Some commenters appeared to assume the study was accounting for all other Part A and Part B costs outside of these categories, which is not the case. Several commenters incorrectly assumed that the Axelrod et al. (2018) study did not include the costs of death on the waiting list; however, the mean costs of death were included in the authors' modeling for the following: death after transplantation, death on the waiting list, and death with function.

In addition to the type of costs included in the Axelrod et al. (2018) study, another reason why we cannot make direct comparisons to the USRDS data is that the Axelrod et al. (2018) study used two sources for their economic data: (1) Medicare claims data from the USRDS and estimates from a novel data set linking national registry data; and (2) hospital cost-accounting data from the University HealthSystem Consortium corporation. The authors explained that the latter source was included because Medicare diagnosis-related group (DRG)-based payments are poorly correlated with the actual cost of the transplantation procedure. In response, we investigated using hospital reported costs instead of Medicare paid amounts for transplant costs for our savings to Medicare estimate calculation. We found that this only made a material difference for some of the living donor kidney transplants, which are expected to be very small percentage of increased transplants in the model, so we did not see a need to adjust our assumptions in response to this detail.

Last, we considered additional factors that could potentially impact our estimate. Medicare spending extraneous to dialysis/transplant could be increased by transplantation because of positive impacts on longevity, for example, but on the other hand Medicare spending could be reduced to the extent that non-disabled recipients under the age of 65 would return to private health insurance after transplant. These (and other) opposing forces could push the average net Medicare impact materially higher or lower than the strict comparison in Axelrod et al. (2018). This is highly dependent on the mix of organs and patients that ultimately represent the increased transplant population in the model. Significant continued uncertainty in these areas necessitates a wide range for assuming the net spending impact per new transplant, and revisiting the evidence did not convince us the range should necessarily be updated in either direction.

Comment: A commenter suggested that there may be an error in Table III of the proposed rule. The commenter stated that the projected $100 million impact on FFS spending should be $105 million (assuming $40,000 per transplant × assuming 2,625 additional transplants = $105,000,000), yielding a mean net savings of $70 million to Medicare after projected net payments of $35 million to IOTA participants.

Response: The commenter incorrectly assumed that the row labeled, ''Impact on FFS Spending'' in Table III of the proposed rule was a direct calculation of the mean savings per transplant multiplied by the number of additional transplants. Instead, we assumed the average Federal spending impact could range from a cautious $20,000 increase to optimistically at most a $100,000 savings per additional transplant with a mode (as well as the mean) assumption being $40,000 savings. The mean of $100,000 reported for the Impact on FFS Spending in the 6-year total column in Table III of the proposed rule is from the average of 400 individual simulation trials, where the savings per additional transplant is a number between $20,000 and $100,000 generated by our actuarial model.

D. Estimated Burden on Participant 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, 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 patient is up to the IOTA participant and will likely vary by IOTA participant, potentially reducing the time to conduct the review. In addition, the patient may decline the review, resulting in the IOTA participant having fewer Medicare waitlist patients than what is used in our estimate.

We estimate that the average IOTA participant would have 200 waitlist patients who are Medicare primary payer or Medicare secondary payer beneficiaries per year and that it would take a clinician 15 minutes to review organ offer acceptance criteria with each patient each year. Using base wage information from BLS for a nurse practitioner (series 29–1171), we estimate the cost of completing these reviews to be $61.78 per hour. The base wage is then doubled [$61.78 × 2] to account for fringe benefits and overhead to equal an estimated cost of $123.56 per hour.[360] The cost of completing these reviews would then be $6,178.00 per hospital per year [200 Medicare waitlist patients × 0.25 hour per review each year × $123.56 hourly wage]. Therefore, the total cost would come out to $556,020.00 to complete the review of organ offer acceptance criteria based on the assumption that 90 active transplant hospitals will be selected as IOTA participants [$6,178.00 × 90 hospitals = $556,020.00]. Average total revenue for the transplant hospitals that may be selected to be an IOTA participant using inpatient hospital codes DRG–008 simultaneous pancreas-kidney transplant and DRG–652 kidney transplant generated from adult Medicare FFS beneficiaries with Medicare as their primary payer was $1.0 million in calendar year (CY) 2023. Therefore, the $6,178.00 cost per IOTA participant to review the organ offer acceptance criteria would represent 0.6 percent of the estimated total annual revenue per IOTA participant from

[360] 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.*

DRGs 653 and 008 when Medicare is the primary payer.

E. Regulatory Review Cost Estimation

We estimate the time it will take for a medical and health services manager to review the rule to be 13.33 hours [200,000 words/250 words per minute/60 minutes = 13.33 hours]. Using the wage information from the Bureau Labor of Statistics (BLS) for medical and health service managers (series 11–9111), we estimate that the cost of reviewing this rule is $129.28 per hour, including overhead and fringe benefits.[361] The cost of reviewing the rule would therefore be a $1,723.30 per hospital [13.33 hours × $129.28 per hour = $1,723.30] or a total cost of $155,097.00 [$1,723.30 × 90 hospitals = $155,097.00]. Using information from the OPTN, we estimate 230 active kidney transplant hospitals that are the potential IOTA participants would review this rule for a total cost of $396,359.00 [$1,723.30 per hospital × 230 hospitals = $396,359.00].[362] In addition, the $1,723.30 cost per IOTA participant to complete the regulatory review would represent 0.1 percent of the estimated total annual revenue from DRGs 653 and 008 from adult Medicare FFS beneficiaries with Medicare as their primary payer.

F. Alternatives Considered

The proposed rule in 42 CFR part 512 [CMS–5535–P] dated May 17, 2024 can be used as an example of alternatives considered for the IOTA Model prior to finalizing the rule. The main changes between the proposed rule and final rule are summarized in this section. The Achievement Domain included the following components in the proposed rule which were modified in the final rule:

- The transplant target was the highest number of deceased or living donor kidney transplants performed during baseline years trended forward by the national growth rate.
- The transplant count included a health equity performance adjustment. Any transplants performed for the underserved population identified in the equity paper (uninsured, Medicaid, dual eligible, Medicare LIS, NLDAC-eligible transplants) counted as 1.2 transplants.
- The thresholds used in the points allocation for the transplant targets included five cutoffs with a range of zero to 60 possible points awarded.

In the final rule, these components were changed to—(1) the transplant target was updated to equal to the average number of transplants performed during baseline years trended forward by the national growth rate; (2) the health equity performance adjustment was removed; and (3) the thresholds used in the point allocation for the transplant targets include eight cutoffs with a range of zero to 60 possible points awarded (see Table II).

The Efficiency Domain was finalized as proposed. The Quality Domain included the following components in the proposed rule which were modified in the final rule: (1) a Quality Measures Set (10 possible points) that included the CollaboRATE Shared Decision-Making Score, a 3-Item Care Transition Measure, and Colorectal Cancer Screening; and (2) a Composite Graft Survival Rate (10 possible points) was based on performance relative to national ranking with five cutoffs and a range of zero to 10 possible points awarded. In the final rule these components were changed to: (1) the Quality Measures Set was removed; and (2) the Composite Graft Survival Rate (20 possible points) is based on performance relative to target with six cutoffs and a range of 10 to 20 possible points awarded (see Table IV).

Last, for the payment methodology, the following component in the proposed rule was modified in the final rule: The maximum upside risk payment was $8,000 and downside risk payment was $2,000. In the final rule, this component was changed to: The maximum upside risk payment was increased to $15,000 and the maximum downside risk payment remained at $2,000 (see equations 7 and 8).

When these components were implemented together in modeling the proposed rule, the mean net projected savings of the IOTA Model totaled $65 million over 6 years, ranging from a savings of $151 million to a cost of $11 million at the 10th and 90th percentiles. Although the mean projected savings decreased after accounting for the final rule policies, significantly increased incentives are expected to increase the number of new transplants generated by the model and create a potential for slightly greater overall savings at the optimistic end of the projection range (the final rule 10th percentile is $152 million savings). Detailed explanation for why these model components changed from the proposed rule to the final rule is provided throughout various sections of the final rule.

Comment: A commenter requested that CMS predict what savings in the model would be if we were to include a pre-emptive transplant multiplier that would drive an uptick in pre-emptive transplantation and related savings.

Response: In the proposed rule, we stated that we considered offering differential credit for transplants by type. With this methodology, IOTA participants would receive bonus points and score higher for transplants that fit into categories that lead to more savings, such as living donor kidney transplants (LDK), high KDPI donors, or pre-emptive transplants, compared to other transplants. Addressing the comment directly, the pre-emptive nature of some transplants is only one of many complex and uncertain factors contributing to the financial impact of the average transplant potentially added in response to model incentives. However, we believe that counting all transplants the same would maximize flexibility for transplant hospitals in meeting their targets and minimizes the potential harm and unintended consequences the alternative system would create. Therefore, a pre-emptive transplant multiplier was not included in the final rule.

G. Impact on Beneficiaries

The upside and downside risk payments in this model are expected to at least marginally increase the number of kidney transplants provided to beneficiaries with ESRD. This model is projected to result in approximately 3,700 new transplants over the 6-year model performance period. Evidence shows that kidney transplants extend patients' lives and that such benefits have been increasing despite unfavorable trends in terms of donor and recipient risk factors.[363] Even if added transplants most often were to involve high Kidney Donor Profile Index (KDPI) organs (that are most often discarded historically), the average recipient would still be expected to benefit from increased quality of life and longevity.[364] In addition—though we did not explicitly assume specific benefits to beneficiaries—the model would include quality measures aimed at improving outcomes even for transplants that would have otherwise occurred absent the model. IOTA participants would be incentivized to improve the composite graft survival rate. The model could also improve the

[361] Bureau of Labor Statistics (BLS). May 2023. ''Occupational Employment and Wage Statistics.'' *https://www.bls.gov/oes/current/oes_nat.htm.*

[362] *https://optn.transplant.hrsa.gov.*

[363] Hariharan S, Irani AK, Danovitch G (2023). ''Long-Term Survival after Kidney Transplantation.'' *New England Journal of Medicine.* 385:729–43. *https://www.nejm.org/doi/full/10.1056/NEJMra2014530.*

[364] Axelrod DA, Schnitzler MA, Xiao H, et al. 2018. ''An Economic Assessment of Contemporary Kidney Transplant Practice.'' *American Journal of Transplantation* 18: 1168–1176. *https://pubmed.ncbi.nlm.nih.gov/29451350/.*

efficiency with which hospitals interact with organ procurement organizations and reduce the time from deceased organ donation to transplant surgery. These and other elements of the model have the potential to improve outcomes for the wider group of transplant patients beyond the fraction assumed to receive transplants under the model.

H. Accounting Statement and Table

The annualized monetized benefits and transfers in Table VI were calculated based on constant payments and constant discount interest rates. Using the row labeled Total as an example for how the results were calculated, the primary estimate of $4 million in total savings was based on a 2 percent discount rate, with a 6-year study period, and a net present value of $24 million in savings. Net present value for the primary estimate was based on the IOTA Model's mean net savings estimate for years July 1, 2025 through June 30, 2031 reported in the bottom row of Table V. The minimum and maximum annualized monetized total benefits and transfers reported in Table VI use the same calculation as the primary estimate, with the exception of the annual mean net savings replaced with the IOTA Model's annual mean net savings for the 10th and 90th percentiles.

TABLE VI: ACCOUNTING STATEMENT

Annualized monetized benefits and transfers (negative indicates savings). Dollars in millions.

	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
Costs to Medicare for Upside Risk Payments to IOTA Participants	$19	$14	$25	RIA Table V
Costs to IOTA Participants for Downside Risk Payments	$0	$0	$0	RIA Table V
Benefits via Savings from Increased Transplants	-$24	-$44	-$6	RIA Table V
Total	**-$4**	**-$25**	**$14**	**RIA Table V**

Notes: The total may not equal the sum of the preceding rows due to rounding. The costs to IOTA participants for negative payments are less than a million dollars for the primary, minimum, and maximum estimates.

TABLE VII: ADDITIONAL ESTIMATED COSTS FOR 2025-2031

Total costs reported for all IOTA participants. Dollars are not reported in millions.

Category	Costs	Frequency	Source Citation
Burden to IOTA participants	$556,020	Annual	Section IV.D. Estimated Burden on Participant Hospitals
Regulatory review	$396,359	One-time	Section IV.E. Regulatory Review Cost Estimation

I. Regulatory Flexibility Act (RFA)

Effects on IOTA participants in the model include the potential for additional upside risk payments from CMS to the IOTA participant of up to $15,000 per eligible kidney transplant or downside risk payments from the IOTA participant to CMS of up to $2,000 per eligible kidney transplant (refer to section IV.C. of this final rule (Detailed Economic Analysis) 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 $1 million in total downside risk payments are expected over 6 years spread across approximately 16 to 18 percent of IOTA participants expected to be charged downside risk payments from year to year. By contrast, we project over 6 years that $117 million in total upside risk payments would be made to between 33 to 43 percent of IOTA participants expected to earn payments in the model from year to year.

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 $8.0 million to $41.5 million in any 1 year). Although many IOTA participants (that is, 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 notably is expected to be a very rare outcome in general) would not represent a significant economic impact. Additional sources of financial burden on IOTA participants to consider include the estimated cost of $6,178.00 per IOTA participant per year to review the organ offer acceptance criteria with IOTA waitlist patients who are Medicare beneficiaries and the one-time cost of $1,723.00 per IOTA participant to have their medical and health services manager review this rule. Refer to the section titled, ''Estimated Burden on Participant Hospitals'' in the final rule for an explanation of how these burden estimates were determined. No comments were received during the public comment period on the RFA section on regulatory relief for small entities.

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 $6,178.00 cost per IOTA participant to review the organ offer acceptance criteria and the $1,723.30 cost per IOTA participant to complete the regulatory review would represent 0.6 percent and 0.1 percent, respectively, of the estimated total annual revenue per IOTA participant from DRGs 653 and 008 when Medicare is the primary payer. 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 603604 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 will not have a significant impact on small rural hospitals since small rural hospitals do not have the resources to perform kidney transplants. 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.

J. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately $183 million. This final rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

K. 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.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 23, 2024.

List of Subjects in 42 CFR Part 512

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

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

■ 1. The part heading for part 512 is revised to read as follows:

PART 512—STANDARD PROVISIONS FOR MANDATORY INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR THE RADIATION ONCOLOGY MODEL AND THE END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

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

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

■ 3. The heading of subpart A is revised to read as follows:

Subpart A—Standard Provisions for Mandatory Innovation Center Models

■ 4. Revise § 512.100 to read as follows.

§ 512.100 Basis and scope.

(a) *Basis.* This subpart implements standard provisions for certain Innovation Center models, as that term is defined in this subpart.

(b) *Scope.* (1) The regulations in this subpart apply to the Radiation Oncology Model implemented under subpart B, the End-Stage Renal Disease (ESRD) Treatment Choices Model implemented under subpart C, and each Innovation Center model for which participation by Model participants is mandatory that begins its first performance period on or after January 1, 2025.

(2) This subpart sets forth the following:

(i) Basis and scope.

(ii) Definitions.

(iii) Beneficiary protections.

(iv) Cooperation in model evaluation and monitoring.

(v) Audits and record retention.

(vi) Rights in data and intellectual property.

(vii) Monitoring and compliance.

(viii) Remedial action.

(ix) Innovation Center model termination by CMS.

(x) Limitations on review.

(xi) Miscellaneous provisions on bankruptcy and other notifications.

(xii) Reconsideration review processes.

(3) Except as specifically noted in this subpart, these regulations do not affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including provisions regarding payment, coverage, or program integrity.

■ 5. Section 512.110 is amended by—

■ a. Adding, in alphabetical order, the definition of ''Governing documentation'';

■ b. Revising the definitions of ''Innovation Center model,'' ''Innovation Center model activities,'' ''Model beneficiary,'' and ''Model participant''; and

■ c. Adding, in alphabetical order, the definitions of ''Performance period'' and ''Standard provisions for Innovation Center models''.

The additions and revisions read as follows:

§ 512.110 Definitions.

* * * * *

Governing documentation means the applicable Federal regulations, and the model-specific participation agreement, cooperative agreement, and any addendum to an existing contract with CMS, that collectively specify the terms of the Innovation Center model.

* * * * *

Innovation Center model means an innovative payment and service delivery model tested under the authority of section 1115A(b) of the Act, including a model expansion under section 1115A(c) of the Act.

* * * * *

Innovation Center model activities mean any activities affecting the care of model beneficiaries related to the test of the Innovation Center model.

* * * * *

Model beneficiary means a beneficiary attributed to a model participant or otherwise included in an Innovation Center model.

* * * * *

Model participant means an individual or entity that is identified as a participant in the Innovation Center model.

* * * * *

Performance period means the period of time during which an Innovation Center model is tested and model participants are held accountable for cost and quality of care; the performance period for each Innovation Center model is specified in the governing documentation.

* * * * *

Standard provisions for Innovation Center models mean the provisions codified in 42 CFR part 512 subpart A.

* * * * *

■ 6. Section 512.190 is added to read as follows:

§ 512.190 Reconsideration review process.

(a) *Applicability of this section.* Section 512.190 is only applicable to the following:

(1) Innovation Center models that have waived section 1869 of the Act, or where section 1869 of the Act is not applicable for model participants.

(2) Model participants, unless the governing documentation for the Innovation Center model states otherwise.

(b) *Right to reconsideration.* The model participant may request reconsideration of a determination made by CMS in accordance with an Innovation Center model's governing documentation only if such reconsideration is not precluded by section 1115A(d)(2) of the Act, this subpart, or the governing documentation for the Innovation Center model for which CMS made the initial determination.

(1) A request for reconsideration by the model participant must satisfy all of the following criteria:

(i) Must be submitted to a designee of CMS (reconsideration official) who—

(A) Is authorized to receive such requests; and

(B) Did not participate in the determination that is the subject of the reconsideration request, or, if applicable, the timely error notice review process.

(ii)(A) Must include a copy of the initial determination issued by CMS; and

(B) Must contain a detailed, written explanation of the basis for the dispute, including supporting documentation.

(iii) Must be made within 30 days of the date of the initial determination for which reconsideration is being requested via email to an address as specified by CMS in the governing documentation for the Innovation Center model for which CMS made the initial determination.

(2) Requests that do not meet the requirements of paragraph (b)(1) of this section are denied.

(3) Within 10 business days of receiving a request for reconsideration, the reconsideration official sends CMS and the model participant a written acknowledgement of receipt of the reconsideration request. This acknowledgement sets forth all of the following:

(i) The review procedures.

(ii) A schedule that permits each party to submit position papers and documentation in support of the party's position for consideration by the reconsideration official.

(4) If the request is regarding a model-specific payment and the governing documentation specifies an initial timely error notice process, the model participant must satisfy the timely error notice requirements specified in the governing documentation before submitting a reconsideration request under paragraph (b) of this section. In the event that the model participant fails to timely submit an error notice with respect to a particular model-specific payment, the reconsideration review process would not be available to the model participant with regard to that model-specific payment.

(c) *Standards for reconsideration.* (1) The parties must continue to fulfill all responsibilities and obligations under the governing documentation during the course of any dispute arising under the governing documentation.

(2) The reconsideration consists of a review of documentation that is submitted timely and in accordance with the standards specified by the reconsideration official and are enumerated in paragraph (b)(3) of this section.

(3) The burden of proof is on the model participant to demonstrate to the reconsideration official with clear and convincing evidence that the determination is inconsistent with the terms of the governing documentation.

(d) *Reconsideration determination.* (1) The reconsideration determination is based solely upon both of the following:

(i) Position papers and supporting documentation that meet both of the following:

(A) Submitted timely to the reconsideration official in accordance with the schedule specified in paragraph (b)(3)(ii) of this section.

(B) The standards for submission under paragraph (b)(1) of this section.

(ii) Documents and data that were timely submitted to CMS in the required format before CMS made the determination that is the subject of the reconsideration request.

(2)(i) The reconsideration official issues the reconsideration determination to CMS and to the model participant in writing.

(ii) Absent unusual circumstances, in which case the reconsideration official reserves the right to an extension upon written notice to the model participant, the reconsideration determination is issued within 60 days of receipt of timely filed position papers and supporting documentation in accordance with the schedule specified in paragraph (b)(3)(ii) of this section.

(3) The reconsideration determination is final and binding 30 days after its issuance, unless the model participant or CMS timely requests review of the reconsideration determination in accordance with paragraphs (e)(1) and (2) of this section.

(e) *CMS Administrator review.* The model participant or CMS may request that the CMS Administrator review the reconsideration determination. The request must meet both of the following:

(1) Be made via email within 30 days of the date of the reconsideration determination to the address specified by CMS.

(2) Include a copy of the reconsideration determination and a detailed written explanation of why the model participant or CMS disagrees with the reconsideration determination.

(3) The CMS Administrator promptly sends the parties a written acknowledgement of receipt of the request for review.

(4) The CMS Administrator sends the parties notice of the following:

(i) Whether the request for review is granted or denied.

(ii) If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party's position for consideration by the CMS Administrator.

(4) If the request for review is denied, the reconsideration determination is final and binding as of the date the request for review is denied.

(5) If the request for review is granted all of the following occur:

(i) The record for review consists solely of—

(A) Timely submitted briefs and the evidence contained in the record of the proceedings before the reconsideration official; and

(B) Evidence as set forth in the documents and data described in paragraph (d)(1)(ii) of this section.

(ii) The CMS Administrator reviews the record and issues to CMS and to the model participant a written determination.

(iii) The written determination of the CMS Administrator is final and binding as of the date the written determination is sent.

■ 7. Adding Subpart D to read as follows:

Subpart D—Increasing Organ Transplant Access (IOTA) Model

Sec.

Subpart D—Increasing Organ Transplant Access (IOTA) Model

§ 512.400 Basis and scope.

(a) *Basis.* This subpart implements the test of the Increasing Organ Transplant Access (IOTA) Model under section 1115A(b) of the Act.

(b) *Scope.* This subpart sets forth the following:

(1) The method for selecting IOTA participants.

(2) The patient population.

(3) The methodology for IOTA participant performance assessment and scoring for purposes of the achievement domain, efficiency domain, and quality domain, including beneficiary attribution and transplant target calculation.

(4) The schedule and methodologies for the upside risk payment and downside risk payment.

(5) Data sharing.

(6) Other IOTA Model requirements.

(7) Beneficiary protections.

(8) Financial arrangements.

(9) Monitoring.

(10) Evaluation.

(11) Termination.

(12) Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other provisions affecting providers and suppliers under Medicare fee for service, including the applicability of provisions regarding payment, coverage, or program integrity.

(c) *Applicability.* IOTA participants are subject to the standard provisions for Innovation Center models specified in subpart A of this part 512 and in subpart K of part 403 of this chapter.

§ 512.402 Definitions.

For purposes of this subpart, the following definitions apply.

Achievement domain means the performance assessment category in which CMS assesses the IOTA participant's performance based on the number of transplants performed relative to the transplant target.

Alignment payment means a payment from an IOTA collaborator to an IOTA participant that is made in accordance with a sharing arrangement.

Annual attribution reconciliation means the yearly process in which CMS—

(1) Creates the final list of each IOTA participant's attributed patients for the prior performance year by retrospectively de-attributing from each IOTA participant any attributed patients that satisfy a criterion for de-attribution under § 512.414(c); and

(2) Creates a final list of each IOTA participant's attributed patients who remain attributed for the performance year being reconciled, subject to the attribution criteria under §§ 512.414(b)(1) and (2).

Annual attribution reconciliation list means the final cumulative record of attributed patients that CMS generates annually for whom each IOTA participant is accountable for during the applicable PY as described at § 512.414(c)(2).

Attributed patient means an IOTA waitlist patient or an IOTA transplant patient.

Attribution means the process by which CMS identifies the patients for whom each IOTA participant is accountable during the model performance period, as described in § 512.414.

Baseline year means a 12-month period within a 3-year historical baseline period, that begins 48 months (or 4 years) before the start of each model PY and ends 12 months (or 1 year) before the start of each model PY, as described in § 512.424.

Bypassed response means an organ offer not received due to expedited placement or a decision by a kidney transplant hospital to have all of its kidney transplant waitlist patients skipped during the organ allocation process based on a set of pre-defined filters selected by the kidney transplant hospital matching the characteristics of the potential organ to be transplanted.

Critical access hospital (CAH) means a hospital as defined in section 1861(mm)(1) of the Act.

Change in control means at least one of the following:

(1) The acquisition by any ''person'' (as this term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the IOTA participant representing more than 50 percent of the IOTA participant's outstanding voting securities or rights to acquire such securities.

(2) The acquisition of the IOTA participant by any other individual or entity.

(3) Any merger, division, dissolution, or expansion of the IOTA participant.

(4) The sale, lease, exchange, or other transfer (in one transaction or a series of transactions) of all or substantially all the assets of the IOTA participant.

(5)(i) The approval and completion of a plan of liquidation of the IOTA participant; or

(ii) An agreement for the sale or liquidation of the IOTA participant.

Collaboration agent means an individual or entity that is not an IOTA collaborator and that is a member of a PGP, NPPGP, or TGP that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is an IOTA collaborator.

Composite graft survival rate means the rolling unadjusted total number of functioning grafts relative to the total number of adult kidney transplants performed, as described in § 512.428.

CORF stands for comprehensive outpatient rehabilitation facility.

Days means calendar days unless otherwise specified by CMS.

Distribution arrangement means a financial arrangement between an IOTA collaborator that is an PGP, NPPGP, or TGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the PGP, NPPGP, or TGP.

Distribution payment means a payment from an IOTA collaborator that is a PGP, NPPGP, or TGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments.

Donation service area (DSA) means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area (MSA) or does not include any part of such an area and that meets the standards of 42 CFR part 486 subpart G as defined in 42 CFR 486.302.

Downside risk payment means the lump sum payment the IOTA participant must pay to CMS after the close of a performance year if the IOTA participant's final performance score falls within the ranges specified in § 512.430.

Efficiency domain means the performance assessment category in which CMS assesses the IOTA participant's performance using the organ offer acceptance rate ratio as described in § 512.426.

EFT stands for electronic funds transfer.

Eligible attributed patient means an attributed patient that receives immunosuppressive drug coverage through Part B or Part D but that does not have secondary insurance that could provide cost sharing support.

Final performance score means the sum total of the scores earned by the IOTA participant across the achievement domain, efficiency domain, and quality domain for a given PY.

Gainsharing payment means a payment that is made from an IOTA participant to an IOTA collaborator, under a sharing arrangement as set forth in § 512.452 and in accordance with § 512.452(c).

Health equity goals mean the targeted outcomes relative to the health equity plan performance measures for the first PY and all subsequent PYs.

Health equity plan intervention means the initiative(s) the IOTA participant creates and implements to reduce target health disparities.

Health equity plan performance measure(s) means one or more quantitative metrics that the IOTA participant uses to measure the reductions in target health disparities arising from the health equity plan interventions.

Health equity project plan means the timeline for the IOTA participant to implement the IOTA participant's health equity plan.

HHA means a Medicare-enrolled home health agency.

Hospital has the meaning set forth in section 1861(e) of the Act.

Improvement benchmark rate means 120 percent of the IOTA participants' performance on the organ offer acceptance rate ratio as specified under § 512.426(c)(1)(ii)(A).

Initial attribution means the process by which CMS identifies and prospectively attributes patients who meet the criteria specified under § 512.414(a)(2)(b) to an IOTA participant prior to the model start date.

IOTA activities mean the activities related to promoting accountability for the quality, cost, and overall care for attributed patients and performance across the achievement domain, efficiency domain and quality domain, including any of the following:

(1) Managing and coordinating care.

(2) Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

(3) The provision of items and services pre- or post-transplant in a manner that reduces costs and improves quality.

(4) Carrying out any other obligation or duty under the IOTA Model.

IOTA collaborator means the following Medicare-enrolled providers and suppliers that enter into a sharing arrangement with an IOTA participant:

(1) Nephrologist.

(2) ESRD facility.

(3) Skilled nursing facility (SNF).

(4) Home health agency (HHA).

(5) Long-term care hospital (LTCH).

(6) Inpatient rehabilitation facility (IRF).

(7) Physician.

(8) Nonphysician practitioner.

(9) Therapist in a private practice.

(10) CORF.

(11) Provider or supplier of outpatient therapy services.

(12) Physician group practice (PGP).

(13) Hospital.

(14) CAH.

(15) Non-physician provider group practice (NPPGP).

(16) Therapy group practice (TGP).

IOTA participant means a kidney transplant hospital, as defined at § 512.402, that is required to participate in the IOTA Model under § 512.412.

IOTA transplant patient means a kidney transplant patient who receives a kidney transplant at the age of 18 years of age or older from an IOTA participant at any time during the model performance period and meets the criteria set forth in § 512.414(b)(2).

IOTA waitlist patient means a kidney transplant waitlist patient, regardless of payer type and waitlist status, who meets all of the following:

(1) Is alive.

(2) 18 years of age or older.

(3) Registered on a waitlist (as defined in § 512.402) to one or more IOTA participants, as identified by the OPTN computer match program.

IRF stands for inpatient rehabilitation facility which must meet all of the following:

(1) The general criteria set forth in § 412.22.

(2) The criteria to be classified as a rehabilitation hospital or rehabilitation unit set forth in §§ 412.23(b), 412.25, and 412.29 for exclusion from the inpatient hospital prospective payment systems specified in § 412.1(a)(1).

Kidney transplant means the procedure in which a kidney is surgically transplanted from a living or deceased donor to a transplant recipient, either alone or in conjunction with any other organ(s).

Kidney transplant hospital means a transplant hospital with a Medicare approved kidney transplant program.

Kidney transplant patient means a patient who was a transplant candidate, as defined in § 121.2, and received a kidney transplant furnished by a kidney transplant hospital, regardless of payer type.

Kidney transplant waitlist patient means a patient who is a transplant candidate, as defined in § 121.2, and who is registered to a waitlist for a kidney at one or more kidney transplant hospitals.

LTCH stands for long-term care hospital that meets the requirements as stated in 42 CFR part 483 subpart B.

Match run means a computerized ranking of transplant candidates based upon donor and candidate medical compatibility and criteria defined in OPTN policies.

Medicare kidney transplant means a kidney transplant furnished to a attributed patient in the IOTA Model whose primary or secondary insurance is Medicare fee for service (FFS), as identified in Medicare FFS claims with MS–DRGs 008, 019, 650, 651, and 652.

Member of the NPPGP or *NPPGP member* means a nonphysician practitioner or therapist who is an owner or employee of an NPPGP and who has reassigned to the NPPGP their right to receive Medicare payment.

Member of the PGP or *PGP member* means a physician, nonphysician practitioner, or therapist who is an owner or employee of the PGP and who has reassigned to the PGP their right to receive Medicare payment.

Member of the TGP or *TGP member* means a therapist who is an owner or employee of a TGP and who has reassigned to the TGP their right to receive Medicare payment.

Missing responses means organ offers that a kidney transplant hospital received from the OPO but did not submit a response (accepting or rejecting) in the allotted 1-hour timeframe from the time the offer was made per OPTN policy 5.6.B.

Model performance period means the 72-month period from the model start date and is comprised of 6 individual performance years.

Model-specific payment means a payment made by CMS only to IOTA participants, or a payment adjustment made only to payments made to IOTA participants, under the terms of the IOTA Model that is not applicable to any other providers or suppliers and includes, unless otherwise specified, both of the following:

(1) The IOTA Model upside risk payment.

(2) The IOTA Model downside risk payment.

Model start date means the date on which the model performance period begins, July 1, 2025.

National growth rate means the percentage increase or decrease in the number of kidney transplants performed over a 12-month period by all kidney transplant hospitals except for pediatric kidney transplant hospitals, as defined at § 512.402.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in accordance with 45 CFR part 162.

Neutral zone means the final performance score range in which the IOTA participant neither owes a downside risk payment to CMS nor receives an upside-risk payment from CMS, in accordance with § 512.430(b)(2).

Non-pediatric facility means a kidney transplant hospital that furnishes more than 50 percent of their kidney transplants annually to patients 18 years of age or older.

Nonphysician practitioner means (except for purposes of 42 CFR part 510 subpart G) one of the following:

(1) A physician assistant who satisfies the qualifications set forth at § 410.74(a)(2)(i) and (ii) of this chapter.

(2) A nurse practitioner who satisfies the qualifications set forth at § 410.75(b) of this chapter.

(3) A clinical nurse specialist who satisfies the qualifications set forth at § 410.76(b) of this chapter.

(4) A certified registered nurse anesthetist (as defined at § 410.69(b)).

(5) A clinical social worker (as defined at § 410.73(a)).

(6) A registered dietician or nutrition professional (as defined at § 410.134).

NPPGP means an entity that is enrolled in Medicare as a group practice, includes at least one owner or employee who is a nonphysician practitioner, does not include a physician owner or employee, and has a valid and active TIN.

OPTN computer match program means a set of computer-based instructions which compares data on a cadaveric organ donor with data on transplant candidates on the waiting list and ranks the candidates according to OPTN policies to determine the priority for allocating the donor organ(s).

Organ procurement and transplantation network or *OPTN* means the network established under section 372 of the Public Health Service Act.

Organ procurement organization or *OPO* means an entity designated by the Secretary under section 1138(b) of the Act and under 42 CFR 486.304.

Part B and Part D immunosuppressive drug cost sharing support means cost sharing support related to immunosuppressive drugs covered by Medicare Part B, the Medicare Part B Immunosuppressive Drug Benefit (Part B–ID), or Medicare Part D that is provided by an IOTA participant to an eligible attributed patient as codified at § 512.456.

Pediatric kidney transplant hospital means a kidney transplant hospital that performs 50 percent or more of its transplants in a 12-month period on patients under the age of 18.

Performance year (PY) means a 12-month period beginning on July 1 and ending on June 30 of each year during the model performance period.

PGP stands for physician group practice.

Physician has the meaning set forth in section 1861(r) of the Act.

Post-transplant period means the 90-day period following an attributed patient's receipt of a kidney transplant.

Preliminary performance assessment and payment calculations means the process by which CMS—

(1) Assesses each IOTA participant's performance in accordance with §§ 512.424, 512.426, 512.428; and

(2) Calculates performance-based payments in accordance with § 512.430.

Provider of outpatient therapy services means an entity that is enrolled in Medicare as a provider of therapy services and furnishes one or more of the following:

(1) Outpatient physical therapy services as defined in § 410.60 of this chapter.

(2) Outpatient occupational therapy services as defined in § 410.59 of this chapter.

(3) Outpatient speech-language pathology services as defined in § 410.62 of this chapter.

Quality domain means 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.

Quality Health Information Network (QHIN) means a network of organizations that agrees to common terms and conditions regarding data exchange with each other (a ''Common Agreement'') and to the functional and technical requirements for such data exchange (as specified in the QHIN Technical Framework or ''QTF'') under section 4003(b) of the 21st Century Cures Act (Pub. L. 114–255).

Quarterly attribution list means the quarterly CMS-generated attributed patient list that CMS provides to the IOTA participant in advance of each quarter during the model performance period in accordance with § 512.414(c)(ii)(2).

Resource gap analysis means the resources needed to implement the health equity plan interventions and identifies any gaps in the IOTA participant's current resources and the additional resources needed.

Scientific Registry of Transplant Recipients or *SRTR* means the registry of information on transplant recipients established under section 373 of the Public Health Service Act.

Selected DSAs means those DSAs selected by CMS for purposes of selecting kidney transplant hospitals for participation in the IOTA Model.

Sharing arrangement means a financial arrangement to only share the upside risk payment and the downside risk payment lump-sum amount as set forth in § 512.452.

SNF stands for skilled nursing facility that meets all applicable requirements in section of 1819 of the Act.

Target health disparities mean health disparities experienced by one or more communities within the IOTA participant's population of attributed patients that the IOTA participant aims to reduce.

Targeted review process means the process in which an IOTA participant may dispute performance and payment calculations made, and issued, by CMS as set forth in § 512.434.

TGP means an entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee who is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN.

Therapist means one of the following individuals as defined at § 484.4 of this chapter:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

Therapist in private practice means a therapist that complies with one of the following special provisions:

(1) For physical therapists in private practice in § 410.60(c) of this chapter.

(2) For occupational therapists in private practice in § 410.59(c) of this chapter.

(3) For speech-language pathologists in private practice in § 410.62(c) of this chapter.

Taxpayer identification number (TIN) means a Federal taxpayer identification

number or employer identification number as defined by the Internal Revenue Service in 26 CFR 301.6109–1.

Transplant hospital means a hospital that furnishes organ transplants as defined in 42 CFR 121.2.

Transplant physician means a physician who provides non-surgical care and treatment to transplant patients before and after transplant as defined in 42 CFR 121.2.

Transplant program means a component within a transplant hospital which provides transplantation of a particular type of organ as defined in 42 CFR 121.2.

Transplant recipient means a person who has received an organ transplant as defined in 42 CFR 121.2.

Transplant target means the target number of kidney transplants calculated by CMS for the IOTA participant to measure the IOTA participant's performance in the achievement domain, as described in § 512.424.

Underserved communities mean populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life as defined by Executive Order 13985 of January 20, 2021.

Upside risk payment means the lump sum payment CMS makes to an IOTA participant if the IOTA participant's final performance score for a performance year falls within the payment range specified in § 512.430.

Waitlist means a list of transplant candidates, as defined in 42 CFR 121.2, registered to the waiting list, as defined in 42 CFR 121.2, maintained by a transplant hospital in accordance with 42 CFR 482.94(b).

Increasing Organ Transplant Access Model Scope and Participation

§ 512.412 Participant eligibility and selection.

(a) *Participant eligibility.* A kidney transplant hospital is eligible to be selected as an IOTA participant, in accordance with the methodology described in paragraph (c) of this section, if the kidney transplant hospital 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.

(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.

(b) *IOTA participant selection.* CMS uses the following process to select IOTA participants for inclusion in the model.

(1) *DSA stratification criteria.* CMS uses the following criteria to stratify DSAs using the list of DSAs as of January 1, 2024:

(i) Census division of the DSA.

(ii) Total number of adult kidney transplants performed per year across eligible kidney transplant hospitals in the DSA during PY 1's baseline years.

(2) *DSA stratification process.* Prior to sampling DSAs, CMS uses the following steps to group DSAs into mutually exclusive groups.

(i) CMS assigns each DSA to one of the nine Census Divisions. CMS assigns each DSA to the Census Division where the majority of the DSA's population resides. CMS determines each DSA's population, and the share of a DSA's population in the applicable Census Division(s) using data from the 2020 Census.

(A) CMS assigns the Puerto Rico DSA to the South Atlantic Census Divisions.

(B) CMS combines the Middle Atlantic and New England Census Divisions and all DSAs therewithin creating eight groups of Census Divisions.

(ii) CMS identifies all kidney transplant hospitals located in each DSA within each Census Division group.

(iii) For each DSA within its assigned Census Division group, CMS identifies the eligible kidney transplant hospitals using the criteria specified in paragraph (a) of this section.

(iv) Using data from each of the baseline years for PY 1, CMS determines the average number of adult kidney transplants performed annually by eligible transplant hospitals located in each DSA as follows:

(A) Sums the number of adult kidney transplants performed across eligible kidney transplant hospitals in a DSA during each of the baseline years for PY 1; and

(B) Divides each DSA's sum resulting from the calculation in paragraph (b)(2)(iv)(A) of this section by three to determine the average number of adult kidney transplants furnished during the baseline years for PY 1.

(v) CMS separates DSAs in each Census Division group into two mutually exclusive groups of the same size, based on the average number of adult kidney transplants performed annually across the baseline years for PY 1, except where there are an odd number of DSAs within a Census Division group:

(A) DSAs with a higher number of adult kidney transplants per year across the baseline years for PY 1.

(B) DSAs with a lower number of adult kidney transplants per year across the baseline years for PY 1.

(vi) Where there are an odd number of DSAs within a Census Division group CMS uses the methodology set forth in paragraph (b)(3) of this section.

(3) *Random sampling of DSAs.* (i) For each DSA group within a Census Division group containing an odd number of DSAs, CMS randomly selects one DSA and determines its participation in the IOTA Model with a 50 percent probability.

(ii) CMS randomly samples, without replacement, 50 percent of the remaining DSAs in each group within each Census Division group created in paragraph (b)(2)(v) of this section.

(c) *Selection of IOTA participants in selected DSAs.* All eligible kidney transplant hospitals in the selected DSAs are required to participate in the IOTA Model.

(d) *Notification of participation.* CMS notifies IOTA participants of their selection to participate in the IOTA Model in a form and manner chosen by CMS at least 3 months prior to the start of the model performance period.

§ 512.414 P Patient population.

(a) *General.* (1) CMS attributes kidney transplant waitlist patients and kidney transplant patients to IOTA participants based on the attribution criteria as described in paragraphs (b)(1) and (b)(2) of this section, for all of the following purposes:

(i) Sharing Medicare claims data for attributed beneficiaries with IOTA participants.

(ii) Assessing each IOTA participant's performance across the achievement domain, efficiency domain, and quality domain.

(iii) Determining performance-based payments paid to or by IOTA participants.

(2) Once a kidney transplant waitlist patient or kidney transplant patient is attributed to an IOTA participant, that respective patient may not opt out of attribution to an IOTA participant and remains attributed to the IOTA participant for the duration of the model performance period, unless the attributed patient meets the de-attribution criteria under paragraph (b)(3) of this section during annual attribution reconciliation as described in paragraph (b)(3) of this section.

(b) *Patient attribution and de-attribution criteria*—(1) *IOTA waitlist patient attribution.* (i) At the time CMS conducts attribution, as described in

paragraph (c) of this section, if a kidney transplant waitlist patient meets the definition of an IOTA waitlist patient, as defined at § 512.402, CMS attributes the kidney transplant waitlist patient as an IOTA waitlist patient to an IOTA participant.

(2) *IOTA transplant patient attribution.* (i) At the time CMS conducts attribution, as described in paragraph (c) of this section, CMS attributes a kidney transplant patient as an IOTA transplant patient if the kidney transplant patient meets all of the following:

(A) The definition of an IOTA transplant patient, as defined at § 512.402.

(B) Is 18 years of age or older at the time of the patient's kidney transplant.

(C) Is alive.

(3) *De-attribution from an IOTA participant.* During annual attribution reconciliation, CMS uses the fourth quarter attribution list for each IOTA participant and de-attributes any attributed patients who, as of the last day of the PY being reconciled, meet any of the following de-attribution criteria:

(A) An IOTA waitlist patient that was removed from and remains unregistered on an IOTA participant's kidney transplant waitlist.

(B) An IOTA waitlist patient that has died at any point during the PY.

(C) An IOTA transplant patient that has died at any point during the PY.

(D) An IOTA transplant patient who experiences transplant failure at any point during the model performance period and has not rejoined an IOTA participant's kidney transplant waitlist or received another transplant from an IOTA participant before the last day of the respective PY.

(c) *Attribution methodology.* CMS employs the following methodology to attribute kidney waitlist patients and kidney transplant patients to an IOTA participant after identifying all kidney waitlist patients and kidney transplant patients that meet the attribution criteria as specified in paragraphs (b)(1) and (b)(2) of this section:

(1)(i) *Initial attribution.* Prior to the model start date, CMS conducts initial attribution, as defined at § 512.402.

(ii) *Initial attribution list.* (A) CMS provides the initial attribution list to the IOTA participant no later than 15 days prior to the start of PY 1 and in a form and manner as determined by CMS.

(B) The initial attribution list includes a list of IOTA waitlist patients identified through initial attribution, effective on the model start date.

(2)(i) *Quarterly attribution.* CMS conducts attribution, as defined at § 512.402, on a quarterly basis after the model start date, and updates the quarterly attribution list, as defined at § 512.402, for each IOTA participant, except in the event of termination in accordance with § 512.466.

(ii) *Quarterly attribution list.* CMS provides the quarterly attribution list, as defined at § 512.402, to the IOTA participant no later than 15 days prior to the start of each quarter and in a form and manner determined by CMS. The quarterly attribution list includes, at minimum, all of the following:

(A) A list of all newly attributed patients, whose attribution to the IOTA participant becomes effective on the first day of the relevant upcoming quarter.

(B) A list of all attributed patients who continue to be attributed to the IOTA participant from the previous quarter.

(C) The dates in which attribution began, changed, or ended, where applicable for attributed patients.

(D) The attributed patient's data sharing preferences under § 512.440(b).

(3)(i) *Annual attribution reconciliation.* After the fourth quarter of each PY, CMS conducts annual attribution reconciliation as defined at § 512.402.

(ii) *Annual attribution reconciliation list.* CMS provides the annual reconciliation list to the IOTA participant before the second quarter of the following PY. Using the fourth quarter quarterly attribution list for each IOTA participant, the annual attribution reconciliation list identifies, at a minimum, all of the following, where applicable:

(A) A list of all attributed patients who remain attributed to the IOTA participant because they satisfied the attribution criteria under §§ 512.414(b)(1) and (2) for the respective PY.

(B) The dates in which attribution began, changed, or ended, where applicable.

(C) A list of all attributed patients who are de-attributed because they failed to satisfy the attribution criteria under § 512.414(b)(1) and (2).

(D) A list of all attributed patients who are de-attributed because they satisfy a de-attribution criterion under § 512.414(b)(3).

(E) The dates on which each attributed patient satisfied a de-attribution criterion as specified under § 512.414(b)(3).

(F) A list of the de-attribution criterion each attributed patient satisfied under § 512.414(b)(3).

Performance Assessment and Scoring

§ 512.422 Overview of performance assessment and scoring.

(a) *General.* (1) CMS establishes the performances measures described in §§ 512.424, 512.426, and 512.428 to assess IOTA participants in the achievement domain, efficiency domain and quality domain.

(2) CMS assigns each set of metrics within a domain a point value with the total possible points awarded to an IOTA participant across the three domains equaling 100, as described in §§ 512.424, 512.426, and 512.428.

(b) *Data sources.* (1) CMS uses Medicare claims data and Medicare administrative data about beneficiaries, providers, suppliers, and data from the OPTN, to calculate performance for the IOTA participant based on the methodologies under §§ 512.424, 512.426, and 512.428.

(2) CMS may also use model-specific data reported by an IOTA participant to CMS under the IOTA Model to calculate IOTA participant performance in the domains.

§ 512.424 Achievement domain.

(a) *General.* (1) After each PY, CMS calculates the number of kidney transplants that each IOTA participant performed for the respective PY, in accordance with the provisions in paragraph (d) of this section.

(2) CMS compares the number of kidney transplants that an IOTA participant performed during the PY to the IOTA participant's transplant target to determine the IOTA participant's score for the achievement domain.

(b) *Transplant target methodology.* CMS determines the IOTA participant's transplant target for each PY as follows:

(1) *Analysis of baseline years.* CMS analyzes the baseline years for the relevant PY and identifies:

(i) The mean number of deceased donor kidney transplants furnished by the IOTA participant to patients 18 years of age or older across the baseline years, as defined at § 512.402; and

(ii) The mean number of living donor kidney transplants furnished by the IOTA participant to patients 18 years of age or older across the baseline years, as defined at § 512.402.

(2) *Mean of kidney transplants.* CMS sums the numbers in paragraphs (b)(1)(i) and (ii) of this section.

(3) *National growth rate calculation.* CMS calculates the national growth rate, as defined at § 512.402, using the baseline years for the relevant PY as follows:

(i) Subtracts the total number of kidney transplants furnished to patients

18 years of age or older during the second baseline year from the total number of kidney transplants furnished to patients 18 years of age or older during the third baseline year.

(ii) Divides the amount resulting from the calculation in paragraph (b)(3)(i) of this section by the total number of kidney transplants furnished to patients 18 years of age or older during the third baseline year. The resulting amount is the national growth rate for the relevant PY.

(4) *Calculation of transplant target.* If the national growth rate calculated in paragraph (b)(3) of this section is—

(i) Positive, CMS multiples that national growth rate by the sum calculated in paragraph (b)(2) of this section. The resulting amount is an IOTA participant's transplant target for the relevant PY; or

(ii) Negative, CMS does not multiply the national growth rate by the sum calculated in paragraph (b)(2) of this section. The IOTA participant's transplant target for the relevant PY is the sum calculated in paragraph (b)(2) of this section.

(c) *Notification of transplant target.* CMS notifies the IOTA participant of the transplant target by the first day of the start of each PY in a form and manner determined by CMS.

(d) *Calculation of kidney transplants performed during the PY.* (1)(i) After each PY, CMS counts the number of kidney transplants performed by the IOTA participant on patients who were 18 years of age or older at the time of transplant, during the PY.

(ii) CMS identifies kidney transplants performed by the IOTA participant using OPTN data, regardless of payer, and Medicare claims data.

(2) CMS counts each kidney transplant described in paragraph (d)(1) of this section as one transplant.

(e) [Reserved]

(f) *Achievement domain scoring.* For each PY, CMS awards the IOTA participant zero to 60 points for its performance in the achievement domain.

(1) CMS compares the total number of kidney transplants identified under paragraph (d)(2) of this section to the IOTA participant's transplant target, as described in paragraph (b) of this section.

(2) CMS uses the following scoring methodology to determine an IOTA participant's score on the achievement domain.

Table 1 to Paragraph (f)(2)—IOTA Model Achievement Domain Scoring Methodology

Performance Relative to Transplant Target	Lower Bound Condition	Upper Bound Condition	Points Earned
125% of transplant target	Equals 125%	Greater than 125%	60
120% of transplant target	Equals 120%	Less than 125%	55
115% of transplant target	Equals 115%	Less than 120%	50
105% of transplant target	Equals 105%	Less than 115%	40
95% of transplant target	Equals 95%	Less than 105%	30
85% of transplant target	Equals 85%	Less than 95%	20
75% of transplant target	Equals 75%	Less than 85%	10
75% of transplant target	N/A	Less than 75%	0

§ 512.426 Efficiency domain.

(a) *General.* For each PY, CMS assesses each IOTA participant on the metric described in paragraph (b) of this section to determine the IOTA participant's score for the efficiency domain.

(b) *Metric included in the efficiency domain.* For each PY, CMS assesses the IOTA participant on the following metric:

(1) *Organ-offer acceptance rate ratio.* For each PY, CMS calculates the organ-offer acceptance rate ratio by dividing the number of kidneys the IOTA participant accepted by the risk-adjusted number of expected organ-offer acceptances using SRTR's methodology as described in equation 1 to paragraph (b)(1) introductory text of this section.

Equation 1 to Paragraph (b)(1) introductory text: Organ Offer Acceptance Rate Ratio

$$Organ\ Offer\ Acceptance\ Rate\ Ratio = \frac{Number\ of\ Acceptances + 2}{Number\ of\ Expected\ Acceptances + 2}$$

(i) CMS uses both of the following:

(A) SRTR data to calculate the organ-offer acceptance rate ratio.

(B) SRTR's adult kidney model strata risk-adjustment methodology and most available set of coefficients to calculate the number of expected organ-offer acceptances.

(ii) CMS includes all of the following kidney offers when calculating the organ-offer acceptance rate ratio for the IOTA participant:

(A) Offers that are ultimately accepted and transplanted.

(B) Offers to candidates on a single organ waitlist (except for kidney/pancreas candidates that are also listed for kidney alone).

(iii) CMS excludes the following kidney offers when calculating the organ-offer acceptance rate:

(A) Offers with multiple match runs from the same donor combined and duplicate offers.

(B) Offers with no match run acceptances.

(C) Offers that occurred after the last acceptance in a match run.

(D) Offers with a missing or bypassed response.

(E) Offers to multi-organ candidates (except for kidney/pancreas candidates that are also listed for kidney alone).

(c) *Efficiency domain scoring.* For each PY, CMS awards the IOTA participant 0 to 20 points for its performance in the efficiency domain.

(1) *General.* CMS determines the IOTA participant's score for the efficiency domain for each PY by taking the IOTA participant's score for the organ offer acceptance rate ratio, as described under paragraph (c)(2) of this section. This number is the IOTA participant's score for the efficiency domain for the PY.

(2) *Scoring for organ offer acceptance rate ratio.* CMS calculates the IOTA participant's achievement score, as described in paragraph (c)(2)(i) of this section, and improvement score, as described under paragraph (c)(2)(ii) of this section, for the organ offer acceptance rate ratio, compares the IOTA participant's achievement score and improvement score and awards to the IOTA participant the points that correspond to the higher score.

(i) *Achievement scoring.* CMS calculates the IOTA participant's achievement score based on the IOTA participant's performance on organ offer acceptance rate ratio relative to national ranking, including all eligible kidney transplant hospitals, using the scoring methodology described in table 1 to paragraph (c)(1)(i) of this section.

Table 1 to Paragraph (c)(1)(i)—IOTA Model Organ Offer Acceptance Rate Ratio Achievement 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	6
20th Percentile	N/A	Less than 20th percentile	0

(ii) *Improvement scoring.* CMS compares the IOTA participant's organ offer acceptance rate ratio during the PY, calculated as described under paragraph (c)(1)(i) of this section, to the IOTA participant's improvement benchmark rate, calculated as described under paragraph (c)(1)(ii)(A) of this section.

(A) *Improvement benchmark rate.* CMS calculates an improvement benchmark rate for the IOTA participant. To determine an IOTA participant's improvement benchmark rate for a given PY, CMS multiplies an IOTA participant's organ offer acceptance rate ratio during the third baseline year by 120 percent.

(B) *Improvement score calculation.* For each PY, CMS uses the following methodology to determine each IOTA participant's improvement score on the organ offer acceptance rate ratio:

(*1*) If the IOTA participant's organ-offer acceptance rate ratio is greater than or equal to the improvement benchmark rate, CMS awards the IOTA participant 15 points in the efficiency domain.

(*2*) If the IOTA participant's organ offer acceptance rate ratio is equal to or less than the IOTA participant's organ-offer acceptance rate ratio in the third baseline year for that respective PY, CMS awards the IOTA participant 0 points in the efficiency domain.

(*3*) If the IOTA participant's organ offer acceptance rate ratio is greater than the IOTA participant's organ-offer acceptance rate ratio in the third baseline year for that respective PY but less than the improvement benchmark rate, CMS uses the following equation:

Equation 2 to Paragraph (c)(2)(ii)(B)(*3*)—IOTA Model Organ Offer Acceptance Rate Ratio Improvement Scoring Equation

$$15\,x\,\frac{Rate\ Earned\ in\ Performance\ Year\ -Third\ Baseline\ Year\ Rate}{Improvment\ Benchmark\ Rate-Third\ Baseline\ Year\ Rate}$$

§ 512.428 Quality domain.

(a) *General.* For each PY, CMS assesses each IOTA participant on the metric described under paragraph (b)(1) of this section to determine the IOTA participant's quality domain score, as described under paragraphs (c) through (e) of this section, for the quality domain.

(b) *Metrics included in the quality domain.* For each PY, CMS assesses each IOTA participant using the following quality metrics:

(1) *Post-transplant graft survival.* For each PY, CMS calculates an IOTA participant's composite graft survival rate by dividing the cumulative number of all functioning kidney grafts for the IOTA participant's IOTA transplant patients by the cumulative number of all kidney transplants performed by the IOTA participant during the first PY and all subsequent PYs on patients 18 years or older at the time of the transplant, as described in equation 1 to paragraph (b)(1) introductory text of this section.

Equation 1 to Paragraph (b)(1) introductory Text: Composite Graft Survival Rate

$$Composite\ Graft\ Survival\ Rate\ =\ \frac{\#\ of\ Functioning\ Grafts}{\#\ of\ Completed\ Kidney\ Transplants}$$

(i) For the first PY, CMS calculates the IOTA participant's composite graft survival rate based solely on the number of functioning grafts furnished to IOTA transplant patients during that PY and the number of completed kidney transplants during that PY, as described in paragraph (b)(1) of this section.

(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.

(iii) CMS excludes the following from the numerator when calculating the composite graft survival rate:

(A) 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.

(B) Re-transplant.

(C) Death.

(D) Patients who are under the age of 18 years of age at the time of the kidney transplant.

(E) Offers to multi-organ candidates (except for kidney/pancreas candidates that are also listed for kidney alone).

(iv)(A) When calculating the composite graft survival rate, CMS only includes kidney 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.

(B) CMS identifies kidney transplants performed by the IOTA participant using OPTN data, regardless of payer, and Medicare claims data.

(2) [Reserved]

(3) [Reserved]

(c) *Quality domain scoring.* For each PY, CMS awards the IOTA participant zero to 20 points for the IOTA participant's performance in the quality domain, in accordance with the following:

(1) For composite graft survival rate, as described under paragraph (d) of this section, the IOTA participant may receive up to 20 points.

(2) [Reserved]

(d) *Composite graft survival rate scoring.* CMS awards points to the IOTA participant based on the IOTA participant's performance on the composite graft survival rate, as described in paragraph (b)(1) of this section, ranked nationally, inclusive of all eligible kidney transplant hospitals. CMS awards points to the IOTA participant for composite graft survival rate as described in table 1 to paragraph (d) of this section:

Table 1 to Paragraph (d)—IOTA Model Composite Graft Survival Rate Scoring

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
80th Percentile	Equals 80th percentile	Greater than 80th percentile	20
60th Percentile	Equals 60th percentile	Less than 80th percentile	18
40th Percentile	Equals 40th percentile	Less than 60th percentile	16
20th Percentile	Equals 20th percentile	Less than 40th percentile	14
10th Percentile	Equals 10th percentile	Less than 20th percentile	12
10th Percentile	N/A	Less than 10th percentile	10

Payment

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

(a) *General.* CMS determines if an IOTA participant qualifies for an upside risk payment, downside risk payment, or the neutral zone for each PY based on the IOTA participant's final performance score, in accordance with paragraphs (b)(1) through (3) of this section.

(b) *Upside risk payment, neutral zone, and downside risk payment calculation methodology*—(1) *Upside risk payment calculation methodology.* If in PYs 1–6 the IOTA participant's final performance score is 60 points or above, CMS calculates the IOTA participant's upside risk payment as follows:

(i) Subtracts 60 from the IOTA participant's final performance score.

(ii) Divides the amount resulting from the calculation in paragraph (b)(1)(i) of this section by 40.

(iii) Multiplies the amount resulting from the calculation in paragraph (b)(1)(ii) of this section by $15,000.

(iv) Multiplies the amount resulting from the calculation in paragraph (b)(1)(iii) of this section by the total number of Medicare kidney transplants performed by the IOTA participant during the PY.

(2) *Neutral zone.* (i) For PY 1, an IOTA participant with a final performance score below 60 points qualifies for the neutral zone and neither owes a downside risk payment to CMS nor receives an upside risk payment from CMS.

(ii) For PYs 2 through 6, if an IOTA participant's final performance is between 41 to 59 points (inclusive), the IOTA participant qualifies for the neutral zone.

(3) *Downside risk payment calculation methodology.* If an IOTA participant is at or below 40 points in PYs 1 through 6, the IOTA participant qualifies for a downside risk payment. The downside risk payment is calculated as follows:

(i) For PY 1, this paragraph does not apply, and the IOTA participant does not owe a downside risk payment to CMS.

(ii) For PYs 2 through 6, CMS calculates the IOTA participant's downside risk payment as follows:

(A) Subtracts the IOTA participant's final performance score from 40.

(B) Divides the amount resulting from the calculation in paragraph (b)(3)(ii)(A) of this section by 40.

(C) Multiplies the amount resulting from the calculation in paragraph (b)(3)(ii)(B) of this section by $2,000.

(D) Multiplies the amount resulting from the calculation in paragraph (b)(3)(ii)(C) of this section by the total number of Medicare kidney transplants performed by the IOTA participant during the PY to calculate the amount of the IOTA participant's downside risk payment.

(c) [Reserved]

(d) *Upside risk payment and downside risk payment timeline.* (1) CMS conducts and calculates preliminary performance assessment and payment calculations at least 3 to 6 months after the end of each PY.

(2) CMS notifies the IOTA participant of their preliminary performance assessment and payment calculations in a form and manner determined by CMS at least 5 to 9 months after the end of each PY.

(3) CMS gives IOTA participants 30 days to review preliminary performance assessment and payment calculations and request targeted reviews under § 512.434.

(4) CMS notifies the IOTA participant of their final performance score and any associated upside risk payment or downside risk payment at least 30 days after notifying the IOTA participant of their preliminary performance assessment and payment calculations.

(5) *Upside risk payment.* After CMS notifies the IOTA participant of their final performance score and any associated upside risk payment, and by a date determined by CMS, CMS issues the upside risk payment to the tax identification number (TIN) on file for the IOTA participant in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS).

(6) *Downside risk payment.* After CMS notifies the IOTA participant of their final performance score and any associated downside risk payment and by a date determined by CMS, CMS

issues a demand letter to the TIN on file for the IOTA participant in PECOS for any downside risk payment owed to CMS.

(i) CMS includes all of the following details in the demand letter:

(A) IOTA participant performance in the model.

(B) Amount of downside risk payment owed to CMS by the IOTA participant.

(C) How the IOTA participant may make payments to CMS.

(ii) The IOTA participant must pay the downside risk payment to CMS in a single payment at least 60 days after the date which the demand letter is issued.

§ 512.434 Targeted review.

(a) *General.* Subject to the limitations on review in paragraph (c) of this section, an IOTA participant may submit a targeted review request for one or more calculations made, and issued by, CMS within the preliminary performance assessment and payment calculations, if either of the following occur:

(1) The IOTA participant believes an error occurred in calculations due to data quality or other issues.

(2) The IOTA participant believes an error occurred in calculations due to misapplication of methodology.

(b) *Requirements.* The request must satisfy the following criteria:

(1) Be submitted within 30 days, or another time period as specified by CMS, of receiving its preliminary performance assessment and payment calculations from CMS.

(2) Include supporting information in a form and manner as specified by CMS.

(c) *Limitations on review.* (1) CMS does not provide IOTA participants the ability to dispute the policy or methodology, as the targeted review process would be limited to the dispute of calculations. CMS would not consider targeted review requests regarding, without limitation, the following:

(i) The selection of the kidney transplant hospital to be an IOTA participant.

(ii) The attribution of IOTA waitlist patients and the attribution of IOTA transplant patients to the IOTA participant, or to any other kidney transplant hospital selected for participation in the IOTA Model, or to any kidney transplant hospital not selected for participation in the IOTA Model.

(iii) The methodology used for determining the achievement domain, efficiency domain, and quality domain.

(iv) The methodology used for calculating and assigning points for each metric within the achievement domain, efficiency domain, and quality domain.

(v) The methodology used for calculating the payment amount per Medicare kidney transplant paid to an IOTA participant.

(2) CMS may review a targeted review request that includes one or more of the limitations in paragraph (c)(1) of this section, provided that all remaining considerations of the request meet all other criteria for consideration by CMS in this section.

(d) *Targeted review process.* The IOTA participant must submit a request for targeted review in accordance with paragraphs (a) through (c) of this section. The process for a targeted review is as follows:

(1) *Initial and final assessments.* Upon receipt of a targeted review request from an IOTA participant CMS conducts an initial and final assessment as follows:

(i) *Initial assessment.* (A) CMS determines if the targeted review request meets the targeted review requirements in paragraph (b) of this section and contains sufficient information to substantiate the request.

(B) If the request is not compliant with paragraphs (a) through (c) of this section or requires additional information:

(*1*) CMS follows up with the IOTA participant to request additional information in a form and manner as specified by CMS.

(*2*) The IOTA participant must respond within 30 days of CMS's request for additional information in a form and manner as specified by CMS.

(*3*) An IOTA participant's non-responsiveness to the request for additional information from CMS may result in the closure of the targeted review request.

(ii) *Final assessment.* (A) Upon completion of an initial assessment, as described in paragraph (d)(1)(i) of this section, CMS determines whether it erred in calculation, as disputed by the IOTA participant.

(B) If a calculation error is found as a result of an IOTA participant's targeted review request—

(*1*) CMS—

(*i*) Notifies the IOTA participant within 30 days of any findings in a form and manner as specified by CMS; and

(*ii*) Resolves and corrects any resulting error or discrepancy in the amount of the upside risk payment or downside risk payment in a time and manner as determined by CMS.

(*2*) CMS' correction of any error or discrepancy may delay the effective date of an IOTA participant's upside risk payments or downside risk payments.

(2) *Targeted review decisions.* Targeted review decisions made by CMS are final, unless submitted for administrative review as described in § 512.190.

§ 512.436 Extreme and uncontrollable circumstances.

(a) *General.* CMS—

(1) Applies determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the affected area during the PY; and

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

(b) *Downside risk payment.* In the event of an extreme and uncontrollable circumstance, as determined by the Quality Payment Program, CMS may reduce the amount of the IOTA participant's downside risk payment, if applicable, prior to recoupment. CMS determines the amount of the reduction by multiplying the downside risk payment by both of the following:

(1) The percentage of total months during the PY affected by the extreme and uncontrollable circumstance.

(2) The percentage of attributed patients who reside in an area affected by the extreme and uncontrollable circumstance.

Data Sharing

§ 512.440 Data sharing.

(a) *General.* CMS shares certain beneficiary-identifiable data as described in paragraph (b) of this section and certain aggregate data as described in paragraph (c) of this section with IOTA participants regarding attributed patients who are Medicare beneficiaries and performance under the model.

(b) *Beneficiary-identifiable data.* CMS shares beneficiary-identifiable data with IOTA participants as follows:

(1) CMS makes available certain beneficiary-identifiable data described in paragraphs (b)(4) and (5) of this section for IOTA participants to request for purposes of conducting health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of their attributed patients who are Medicare beneficiaries.

(2) An IOTA participant that wishes to receive beneficiary-identifiable data for its attributed patients who are

Medicare beneficiaries must do all of the following:

(i) Submit a formal request for the data, on an annual basis in a manner and form and by a date specified by CMS, which identifies the data being requested and attests that—

(A) The IOTA participant is requesting this beneficiary-identifiable data as a HIPAA covered entity or as a business associate, as those terms are defined at 45 CFR 160.103, to the IOTA participant's providers and suppliers who are HIPAA covered entities; and

(B) The IOTA participant's request reflects the minimum data necessary, as set forth in paragraph (b)(6) of this section, for the IOTA participant to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(ii) Limit the request to Medicare beneficiaries whose name appears on the quarterly attribution list who have been notified in compliance with § 512.450 that the IOTA participant has requested access to beneficiary-identifiable data, and who did not decline having their claims data shared with the IOTA participant as provided in paragraph (b)(7) of this section.

(iii) Sign and submit a data sharing agreement with CMS as set forth in paragraph (b)(8) of this section.

(3) CMS shares beneficiary-identifiable data with an IOTA participant on the condition that the IOTA participant, its IOTA collaborators, and other individuals or entities performing functions or services related to the IOTA participant's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and comply with the terms of the data sharing agreement described in paragraph (b)(8) of this section.

(4) CMS omits from the beneficiary-identifiable data any information that is subject to the regulations in 42 CFR part 2 governing the confidentiality of substance use disorder patient records.

(5) The beneficiary-identifiable data will include, when available, the following information:

(i) *Quarterly attribution lists.* For the relevant PY, CMS shares with the IOTA participant the quarterly attribution lists, which will include but may not be limited to the following information for each attributed patient:

(A) The year that CMS attributed the patient to the IOTA participant.

(B) The effective date of the patient's attribution to the IOTA participant.

(C) The effective date of the patient's de-attribution from the IOTA participant and the reason for such removal (if applicable).

(D) For Medicare beneficiaries, the attributed patient's data sharing preference.

(ii) *Beneficiary-identifiable claims data.* CMS makes available certain beneficiary-identifiable claims data for retrieval by IOTA participants no later than 1 month after the start of each PY, in a form and manner specified by CMS. IOTA participants may retrieve the following data at any point during the relevant PY. This claims data includes all of the following:

(A) Three years of historical Parts A, B, and D claims data files from the 36 months immediately preceding the effective date of each attributed patient who is a Medicare beneficiary's attribution to the IOTA participant.

(B) Monthly Parts A, B, and D claims data files for attributed patients who are Medicare beneficiaries.

(C) Monthly Parts A, B, and D claims data files for Medicare beneficiaries who have been de-attributed from the IOTA participant for claims with a date of service before the date the Medicare beneficiary was de-attributed from the IOTA participant.

(6) The IOTA participant must limit its attributed Medicare beneficiary identifiable data requests to the minimum necessary to accomplish a permitted use of the data.

(i) The minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

(A) Medicare beneficiary identifier (ID).

(B) Procedure code.

(C) Gender.

(D) Diagnosis code.

(E) Claim ID.

(F) The from and through dates of service.

(G) The provider or supplier ID.

(H) The claim payment type.

(I) Date of birth and death, if applicable.

(J) Tax identification number (TIN).

(K) National provider identifier (NPI).

(ii) The minimum necessary Part D data elements may include but are not limited to the following data elements:

(A) Beneficiary ID.

(B) Prescriber ID.

(C) Drug service date.

(D) Drug product service ID.

(E) Quantity dispensed.

(F) Days supplied.

(G) Brand name.

(H) Generic name.

(I) Drug strength.

(J) TIN.

(K) NPI.

(L) Indication if on formulary.

(M) Gross drug cost.

(7)(i)(A) IOTA participants must send Medicare beneficiaries a notification about the IOTA Model and the opportunity to decline claims data sharing as required under § 512.450.

(B) Such notifications must do both of the following:

(*1*) State that the IOTA participant may have requested beneficiary-identifiable claims data about the Medicare beneficiary for purposes of its care coordination, quality improvement work, and population-based activities relating to improving health or reducing health care costs.

(2) Inform the Medicare beneficiary how to decline having his or her claims information shared with the IOTA participant in the form and manner specified by CMS.

(ii) Medicare beneficiary requests to decline claims data sharing remain in effect unless and until a beneficiary subsequently contacts CMS to amend that request to permit claims data sharing with IOTA participants.

(iii) The opportunity to decline having claims data shared with an IOTA participant under paragraph (b)(7)(i) of this section does not apply to any of the following:

(A) The aggregate data that CMS provides to IOTA participants under paragraph (c) of this section.

(B) The initial attribution lists that CMS provides to IOTA participants as defined at § 512.402 and specified under § 512.414(c)(1)(ii).

(C) The quarterly attribution lists that CMS provides to IOTA participants as defined at § 512.402 and specified under § 512.414(c)(2)(ii).

(D) The annual attribution reconciliation list that CMS provides to IOTA participants as defined at § 512.402 and specified under § 512.414(c)(3)(ii).

(8)(i) If an IOTA participant wishes to retrieve any beneficiary-identifiable data specified in paragraph (b) of this section, the IOTA participant must complete and submit, on an annual basis, a signed data sharing agreement, to be provided in a form and manner specified by CMS, under which the IOTA participant agrees to all of the following:

(A) To comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations at 45 CFR part 160 and part 164, subparts A and E, and the requirements of the IOTA Model set forth in this part.

(B) To comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the data sharing agreement.

(C) To contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the IOTA participant, including all IOTA collaborators, to the same terms and conditions to which the IOTA participant is itself bound in its data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the IOTA participant under the IOTA Model.

(D) That if the IOTA participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may do all of the following:

(*1*) Deem the IOTA participant ineligible to retrieve the beneficiary-identifiable data under paragraph (b) of this section for any amount of time.

(*2*) Terminate the IOTA participant's participation in the IOTA Model under § 512.466.

(*3*) Subject the IOTA participant to additional sanctions and penalties available under the law.

(ii) An IOTA participant must comply with all applicable laws and the terms of the data sharing in order to retrieve beneficiary-identifiable data.

(c) *Aggregate data.* (1) CMS shares aggregate performance data with IOTA participants, in a form and manner to be specified by CMS, which has been de-identified in accordance with 45 CFR 164.514(b). This aggregate data includes, when available, certain de-identified data detailing the IOTA participant's performance against the transplant target information for each PY.

§ 512.442 Transparency requirements.

(a) *Publication of transplant patient selection criteria.* 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.

(b) [Reserved]

(c) *Review of acceptance criteria.* IOTA participants must 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.

(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.

(2) [Reserved]

§ 512.446 Health equity plans.

(a) For each PY, an IOTA participant may voluntarily submit a health equity plan, by a date and in a form and manner determined by CMS, that meets the following requirements:

(1) Identifies target health disparities.

(2) Identifies the data sources used to inform the identification of target health disparities.

(3) Describes the health equity plan intervention.

(4) Includes a resource gap analysis.

(5) Includes a health equity project plan.

(6) Identifies health equity plan performance measure(s).

(7) Identifies health equity goals and describes how the IOTA participant will use the health equity goals to monitor and evaluate progress in reducing targeted health disparities.

(b) [Reserved]

Beneficiary Protections and Financial Arrangements, Beneficiary Incentives, and Compliance.

§ 512.450 Required beneficiary notifications.

(a) *General.* (1) IOTA participants must provide notice to attributed patients that they are participating in the IOTA Model.

(2) CMS provides a notification template that IOTA participants must use. The template, at minimum does all of the following:

(i) Indicates content that the IOTA participant must not change.

(ii) Indicates where the IOTA participant may insert its own content.

(iii) Includes information regarding the attributed patient's opportunity to opt-out of data sharing with IOTA participants and how they may opt out if they choose to do so.

(3) To notify attributed patients of their rights and protections and that the IOTA participant is participating in the IOTA Model, the IOTA participant must do all of the following:

(i) Prominently display informational materials in each of their office or facility locations where attributed patients receive treatment.

(ii) Include this notification in a clear manner on its public facing website.

(iii) Provide this notification to each attributed patient in a paper format.

(b) *Applicability of general Innovation Center model provisions.* (1) The requirements described in § 512.120(c) do not apply to the CMS-provided materials described in paragraph (a) of this section.

(2) All other IOTA participant communications that are descriptive model materials and activities as defined under § 512.110 must meet the requirements described in § 512.120(c).

§ 512.452 Financial sharing arrangements and attributed patient engagement incentives.

(a) *General.* (1) The IOTA participant—

(i) May enter into a sharing arrangement with an IOTA collaborator to make a gainsharing payment, or to receive an alignment payment, or both; and

(ii) Must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) The IOTA participant must develop, maintain, and use a set of written policies for selecting providers and suppliers to be IOTA collaborators.

(i) The selection criteria must include the quality of care delivered by the potential IOTA collaborator.

(ii) The selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among any of the following:

(A) The IOTA participant.

(B) Any IOTA collaborator.

(C) Any collaboration agent.

(D) Any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(iii) The written policies must contain criteria related to, and inclusive of, the anticipated contribution to performance across the achievement domain, efficiency domain, and quality domain by the potential IOTA collaborator.

(4) The board or other governing body of the IOTA participant must have responsibility for overseeing the IOTA participant's participation in the IOTA Model, including but not limited to all of the following:

(i) Arrangements with IOTA collaborators.

(ii) Payment of gainsharing payments.

(iii) Receipt of alignment payments.

(iv) Use of beneficiary incentives in the IOTA Model.

(5) If an IOTA participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the IOTA Model.

(b) *Requirements.* (1) A sharing arrangement must be—

(i) In writing;

(ii) Signed by the parties; and

(iii) Entered into before care is furnished to an attributed patient during the PY under the sharing arrangement.

(2) Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(3) Participation in the sharing arrangement must require the IOTA collaborator to comply with the requirements of this model, as those pertain to their actions and obligations.

(4) The sharing arrangement—

(i) Must set out the mutually agreeable terms for the financial arrangement between the parties to guide and reward model care redesign for future performance across the achievement domain, efficiency domain, and quality domain;

(ii) Must not reflect the results of model PYs that have already occurred; and

(iii) Where the financial outcome of the sharing arrangement terms are known before signing.

(5) The sharing arrangement must require the IOTA collaborator and its employees, contractors (including collaboration agents), and subcontractors to comply with all of the following:

(i) The applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees).

(ii) All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement.

(iii) All other applicable laws and regulations.

(6) The sharing arrangement must require the IOTA collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the IOTA Model that apply to its role as an IOTA collaborator, including any distribution arrangements.

(7) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(8) The written agreement memorializing a sharing arrangement must specify all of the following:

(i) The purpose and scope of the sharing arrangement.

(ii) The identities and obligations of the parties, including specified IOTA activities and other services to be performed by the parties under the sharing arrangement.

(iii) The date of the sharing arrangement.

(iv) Management and staffing information, including type of personnel or contractors that would be primarily responsible for carrying out IOTA activities.

(v) The financial or economic terms for payment, including all of the following:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payment.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on performance across the achievement domain, efficiency domain and quality domain, and the provision of IOTA activities.

(E) Methodology and accounting formula for determining the amount of an alignment payment.

(9) The sharing arrangement must not—

(i) Induce—

(A) The IOTA participant;

(B) The IOTA collaborator; or

(C) Any employees, contractors, or subcontractors of the IOTA participant or IOTA collaborator to reduce or limit medically necessary services to any attributed patient; or

(ii) Restrict the ability of an IOTA collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(c) *Gainsharing payments and alignment payments.* (1) Gainsharing payments, if any, must meet all of the following:

(i) Be derived solely from upside risk payments.

(ii) Be distributed on an annual basis (not more than once per performance year).

(iii) Not be a loan, advance payment, or payment for referrals or other business.

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2) To be eligible to receive a gainsharing payment an IOTA collaborator must contribute to performance across the achievement domain, efficiency domain or quality domain for the PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment. The contribution to performance across the achievement domain, efficiency domain, or quality domain criteria must be established by the IOTA participant and directly related to the care of attributed patients.

(3) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment:

(i) An IOTA collaborator other than PGP, NPPGP, or TGP must have directly furnished a billable item or service to an attributed patient that occurred in the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment.

(ii) An IOTA collaborator that is a PGP, NPPGP, or TGP must meet the following criteria:

(A) The PGP, NPPGP, or TGP must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively to an attributed patient that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment.

(B) The PGP, NPPGP, or TGP must have contributed to IOTA activities and been clinically involved in the care of attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment.

(4) The total amount of a gainsharing payment for a PY paid to an IOTA collaborator that is a physician or nonphysician practitioner must not exceed 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that physician or nonphysician practitioner to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made.

(5) The total amount of a gainsharing payment for a PY paid to an IOTA collaborator that is a PGP, NPPGP, or TGP must not exceed 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that PGP, NPPGP, or TGP and furnished to the IOTA participant's attributed patients by the PGP members, NPPGP members, or TGP members respectively during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made.

(6) The amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on contribution to the performance across the achievement domain, efficiency domain or quality

domain and the provision of IOTA activities. The methodology may take into account the amount of such IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators.

(7) For a PY, the aggregate amount of all gainsharing payments that are derived from the upside risk payment the IOTA participant receives from CMS must not exceed the amount of that upside risk payment.

(8) No entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(9) An IOTA participant must not make a gainsharing payment to an IOTA collaborator that is subject to any action for noncompliance with this part, or the fraud and abuse laws, or for the provision of substandard care to attributed patients or other integrity problems.

(10) The sharing arrangement must require the IOTA participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on an upside risk payment or was based on the submission of false or fraudulent data.

(11) Alignment payments from an IOTA collaborator to an IOTA participant may be made at any interval that is agreed upon by both parties, and must not be—

(i) Issued, distributed, or paid prior to the calculation by CMS of a payment amount reflected in the notification of the downside risk payment;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by an IOTA participant if the IOTA participant does not owe a downside risk payment.

(12) The IOTA participant must not receive any amounts under a sharing arrangement from an IOTA collaborator that are not alignment payments.

(13) For a PY, the aggregate amount of all alignment payments received by the IOTA participant must not exceed 50 percent of the IOTA participant's downside risk payment amount.

(14) The aggregate amount of all alignment payments from a single IOTA collaborator to the IOTA participant may not be greater than 25 percent of the IOTA participant's downside risk payment over the course of a single PY for an IOTA collaborator.

(15) The amount of any alignment payments must be determined in accordance with a methodology that does not directly account for the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(16) All gainsharing payments and any alignment payments must be administered by the IOTA participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(17) All gainsharing payments and alignment payments must be made by check, EFT, or another traceable cash transaction.

(d) *Documentation requirements.* (1) The IOTA participant must do all of the following:

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement.

(ii) Maintain accurate current and historical lists of all IOTA collaborators, including IOTA collaborator names and addresses. With respect to these lists the IOTA participant must—

(A) Update such lists on at least a quarterly basis; and

(B) On a web page on the IOTA participant's website, the IOTA participant must—

(*1*) Publicly report the current and historical lists of IOTA collaborators; and

(*2*) Include any written policies for selecting individuals and entities to be IOTA collaborators required by the IOTA participant.

(iii) Maintain and require each IOTA collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum all of the following:

(A) Nature of the payment (gainsharing payment or alignment payment).

(B) Identity of the parties making and receiving the payment.

(C) Date of the payment.

(D) Amount of the payment.

(E) Date and amount of any recoupment of all or a portion of an IOTA collaborator's gainsharing payment.

(F) Explanation for each recoupment, such as whether the IOTA collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of an upside risk payment or was based on the submission of false or fraudulent data.

(2) The IOTA participant must keep records of all of the following:

(i) Its process for determining and verifying its potential and current IOTA collaborators' eligibility to participate in Medicare.

(ii) A description of current health information technology, including systems to track upside risk payments and downside risk payments.

(iii) Its plan to track gainsharing payments and alignment payments.

(3) The IOTA participant must retain and provide access to, and must require each IOTA collaborator to retain and provide access to, the required documentation in accordance with §§ 512.460 and 1001.952(ii).

§ 512.454 Distribution arrangements.

(a) *General.* (1) An IOTA collaborator may distribute all or a portion of any gainsharing payment it receives from the IOTA participant only in accordance with a distribution arrangement, as defined at § 512.402.

(2) All distribution arrangements must comply with the provisions of this section and all other applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.* (1) All distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to attributed patients under the distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(5) The amount of any distribution payments from an NPPGP to an NPPGP member, or from a TGP to a TGP member must be determined in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities and that may take into account

the amount of such IOTA activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP must be determined either in a manner that complies with § 411.352(g) of this chapter or in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain and quality domain and the provision of IOTA activities and that may take into account the amount of such IOTA activities provided by a collaboration agent relative to other collaboration agents.

(7) Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to an attributed patient that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed.

(8) Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, the total amount of distribution payments for a PY paid to a collaboration agent must not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by that PGP, NPPGP or TGP for items and services furnished by PGP members, NPPGP members or TGP members respectively to attributed patients that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed.

(9) With respect to the distribution of any gainsharing payment received by a PGP, NPPGP, or TGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the IOTA collaborator from the IOTA participant.

(10) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(11) The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(12) The distribution arrangement must not—

(i) Induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(13) The IOTA collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.454, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any distribution payment(s).

(iii) The identity of each collaboration agent that received a distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The IOTA collaborator may not enter into a distribution arrangement with any collaboration agent that has a sharing arrangement with the same IOTA participant.

(15) The IOTA collaborator must retain and provide access to and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.460.

§ 512.455 Enforcement authority.

(a) *OIG authority.* Nothing contained in the terms of the IOTA Model or this part limits or restricts the authority of the HHS Office of Inspector General, including its authority to audit, evaluate, investigate, or inspect the IOTA participant, IOTA collaborators, or any other person or entity or their records, data, or information, without limitation.

(b) *Other authority.* Nothing contained in the terms of the IOTA Model or this part limits or restricts the authority of any government agency permitted by law to audit, evaluate, investigate, or inspect the participant hospital, IOTA collaborators, or any other person or entity or their records, data, or information, without limitation.

§ 512.456 Beneficiary incentive: Part B and Part D immunosuppressive drug cost sharing support.

(a) *Cost sharing support for Part B and Part D immunosuppressive drugs.* For immunosuppressive drugs covered under Medicare Part B or Medicare Part D and prescribed to an attributed patient, the IOTA participant may subsidize, in whole or in part, the cost sharing associated with the immunosuppressive drugs under Part B and Part D immunosuppressive drug cost sharing support defined at § 512.402 if all of the following conditions are met:

(1) The attributed patient is an eligible attributed patient as defined at § 512.402.

(2) The IOTA participant must provide a written policy in a form and manner specified by CMS for the provision of Part B and Part D immunosuppressive drug cost sharing support that is approved by CMS before the PY in which the cost sharing support is made available.

(i) The IOTA participant must revalidate the written policy with CMS and in a form and manner specified by CMS for the provision of Part B and Part D immunosuppressive drug cost sharing support before its provision in a subsequent PY.

(ii) The IOTA participant's initial written policy and the revalidation of the written policy must establish and justify the criteria that qualify an eligible attributed patient to receive Part B and Part D immunosuppressive drug cost sharing support.

(iii) The IOTA participant's written policy and the revalidation of the written policy must include an attestation that the IOTA participant will not, in providing Part B and Part D immunosuppressive drug cost sharing support, take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patients' choice of pharmacy.

(b) *Restrictions.* (1) An IOTA participant must not take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patients' choice of pharmacy when providing Part B and Part D immunosuppressive drug cost sharing support.

(2) An IOTA participant may not receive financial or operational support for Part B and Part D immunosuppressive drug cost sharing support from pharmacies and pharmaceutical manufacturers.

(c) *Documentation.* (1) An IOTA participant must maintain contemporaneous documentation that includes all of the following:

(i) The identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided.

(ii) The date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided.

(iii) The amount or amounts of Part B and Part B immunosuppressive drug cost sharing support that was provided.

(2) An IOTA participant must retain and make available records pertaining to Part B and Part D immunosuppressive drug cost sharing support to the Federal Government in accordance with § 512.460.

§ 512.458 Attributed patient engagement incentives.

(a) *General.* An IOTA participant may choose to provide any or all of the following types of attributed patient engagement incentives to an attributed patient under the conditions described in paragraph (b) of this section:

(1) Communication devices and related communication services directly pertaining to communication with an IOTA participant or IOTA collaborator to improve communication between an attributed patient and an IOTA participant or IOTA collaborator.

(2) Transportation to and from an IOTA participant and between other providers and suppliers involved in the provision of ESRD care.

(3) Mental health services to address an attributed patient's behavioral health symptoms pre- and post-transplant.

(4) In-home care to support the health of the attributed patient or the kidney transplant in the post-transplant period.

(b) *Conditions.* An IOTA participant may provide attributed patient engagement incentives of the type described in paragraphs (a)(1) through (4) of this section when all of the following conditions are met:

(1) An IOTA participant provides a written policy, in a form and manner specified by CMS, for the provision of attributed patient engagement incentives.

(2) CMS approves an IOTA participants written policy before the first PY in which an attributed patient engagement incentive is first made available.

(3) CMS revalidates the IOTA participant's written policy in a form and manner specified by CMS prior to each PY in which an attributed patient engagement incentive is offered subsequently.

(4) The IOTA participant includes in its written policy:

(i) A description of the items or services that will be provided as attributed patient engagement incentives.

(ii) An explanation of how each item or service that will be an attributed patient engagement incentive has a reasonable connection to any of the following:

(A) An attributed patient achieving and maintaining active status on a kidney transplant waitlist.

(B) An attributed patient accessing the kidney transplant procedure.

(C) The health of the attributed patient or the kidney transplant in the post-transplant period.

(D) A justification for the need for the attributed patient engagement incentives that is specific to the IOTA participant's attributed patient population.

(iii) An attestation that items that are attributed patient engagement incentives will be provided directly to an attributed patient.

(iv) An attestation that the IOTA participant will pay service providers directly for services that are attributed patient engagement incentives.

(v) An attestation that any items or services acquired by the IOTA participant that will be furnished as attributed patient engagement incentives will be acquired for the minimum amount necessary for an attributed patient to achieve the goals described in paragraphs (3)(ii)(A) through (C) of this paragraph.

(c) *Restrictions.* (1) An IOTA participant must provide items that are attributed patient engagement incentives directly to an attributed patient.

(2) An IOTA participant must pay service providers directly for any services that are offered as attributed patient engagement incentive.

(3) An IOTA participant must not offer an attributed patient engagement incentive that is tied to the receipt of items or services from a particular provider or supplier.

(4) An IOTA participant must not advertise or promote an item or service that is an attributed patient engagement incentive, except to make an attributed patient aware of the availability of the items or services at the time an attributed patient could reasonably benefit from them.

(5) An IOTA participant must not receive donations directly or indirectly to purchase attributed patient engagement incentives.

(6) An IOTA participant must retrieve items that that are attributed patient engagement incentives from the attributed patient when the attributed patient is no longer eligible for the that item or at the conclusion of the IOTA Model, whichever is earlier.

(i) Documented, diligent, good faith attempts to retrieve items that are attributed patient engagement incentives are deemed to meet the retrieval requirement.

(ii) [Reserved]

(7) Items that are communication devices:

(i) May not exceed $1,000 in retail value for any one attributed patient in any one PY;

(ii) Must remain the property of the IOTA participant;

(iii) Must be retrieved from the attributed patient by the IOTA participant—

(A) When the attributed patient is no longer eligible for the communication device or at the conclusion of the IOTA Model, whichever is earlier; and

(B) Before another communication device may be made available to the same attributed patient.

(d) *Documentation.* The IOTA participant must do all of the following:

(1) Maintain contemporaneous documentation of items and services furnished as attributed patient engagement incentives that includes, at minimum all of the following:

(i) The date the attributed patient engagement incentive is provided.

(ii) The identity of the attributed patient to whom the item or service was provided.

(2) Document all retrieval attempts of items that are attributed patient engagement incentives, including the ultimate date of retrieval.

(3)(i) Retain records pertaining to furnished attributed patient engagement incentives.

(ii) Make the records available to the Federal Government in accordance with § 512.460.

§ 512.459 Application of the CMS-sponsored Model Arrangements and Patient Incentives Safe Harbor.

(a) *Application of the CMS-sponsored Model Arrangements Safe Harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) is available to protect remuneration furnished in the IOTA Model in the form of the Sharing Arrangement's gainsharing payments, the Sharing Arrangement's alignment payments, and the Distribution Arrangement's distribution payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii), 512.452, and 512.454.

(b) *Application of the CMS-sponsored Model Patient Incentives Safe Harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect remuneration furnished in the IOTA Model in the form of Part B and Part D immunosuppressive drug cost sharing support and the attributed patient engagement incentives that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii), 512.456 and 512.458.

§ 512.460 Audit rights and records retention.

(a) *Right to audit.* The Federal Government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence

regarding implementation of the IOTA Model.

(b) *Access to records.* The IOTA participant and its IOTA collaborators must maintain and give the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, access to all such documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the implementation of the IOTA Model, including without limitation, documents, and other evidence regarding all of the following:

(1) Compliance by the IOTA participant and its IOTA collaborators with the terms of the IOTA Model.

(2) The accuracy of model-specific payments made under the IOTA Model.

(3) The IOTA participant's downside risk payments owed to CMS under the IOTA Model.

(4) Quality measure information and the quality of services performed under the terms of the IOTA Model.

(5) Utilization of items and services furnished under the IOTA Model.

(6) The ability of the IOTA participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

(7) Contemporaneous documentation of cost sharing support furnished under Part B and Part D immunosuppressive drug cost sharing support that includes the following:

(i) The identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided.

(ii) The date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided.

(iii) The amount or amounts of the cost sharing support provided to the attributed patient.

(8) Contemporaneous documentation of items and services furnished as attributed patient engagement incentives in accordance with § 512.458 that includes all of the following, at minimum:

(i) The date the attributed patient engagement incentive is provided.

(ii) The identity of the attributed patient to whom the item or service was provided.

(9) Patient safety.

(10) Any other program integrity issues.

(c) *Record retention.* (1) The IOTA participant and its IOTA collaborators must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of 6 years from the last payment determination for the IOTA participant under the IOTA Model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the IOTA participant at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the IOTA participant or its IOTA collaborators, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(2)(i) If CMS notifies the IOTA participant of the special need to retain a record or group of records in accordance with paragraph (c)(1)(i) of this section, the IOTA participant must maintain the records for such period of time as determined by CMS.

(ii) If CMS notifies the IOTA participant of a special need to retain records in accordance with paragraph (c)(1)(ii) of this section, the IOTA participant must notify its IOTA collaborators of this need to retain records for the additional period specified by CMS.

§ 512.462 Compliance and monitoring.

(a) *Compliance with laws.* The IOTA participant must comply with all applicable laws and regulations.

(b) *CMS monitoring activities.* (1) CMS, or its approved designee, may conduct monitoring activities to ensure compliance by the IOTA participant and IOTA collaborators with the terms of the IOTA Model under this subpart to—

(i) Understand IOTA participants' use of model-specific payments; and

(ii) Promote the safety of attributed patients and the integrity of the IOTA Model.

(2) Monitoring activities may include, without limitation, all of the following:

(i) Documentation requests sent to the IOTA participant and its IOTA collaborators, including surveys and questionnaires.

(ii) Audits of claims data, quality measures, medical records, and other data from the IOTA participant and its IOTA collaborators.

(iii) Interviews with the IOTA participant, including leadership personnel, medical staff, other associates, and its IOTA collaborators.

(iv) Interviews with attributed patients and their caregivers.

(v) Site visits to the IOTA participant and its IOTA collaborators, performed in a manner consistent with paragraph (c) of this section.

(vi) Monitoring quality outcomes and attributed patient data.

(vii) Tracking beneficiary complaints and appeals.

(viii) Monitoring the definition of and justification for the subpopulation of the IOTA participant's eligible attributed patients that may receive Part B and Part D immunosuppressive drug cost sharing support in accordance with § 512.456.

(ix) Monitoring the provision of attributed patient engagement incentives provided in accordance with § 512.458.

(x) Monitoring out of sequence allocation of kidneys by—

(A) Assessing the frequency at which IOTA waitlist patients, top-ranked on an IOTA participant's kidney transplant waitlist, receive the organ that was initially offered to them; and

(B) Determining the reasons behind cases where IOTA waitlist patients identified in paragraph (b)(x)(A) of this section, did not receive the kidney offered to them.

(3) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including without limitation all Medicare claims submitted for items or services furnished to IOTA transplant patients or IOTA waitlist patients or both.

(c) *Site visits.* (1) The IOTA participant must cooperate in periodic site visits performed by CMS or its designees in order to facilitate the evaluation of the IOTA Model in accordance with section 1115A(b)(4) of the ACT and the monitoring of the IOTA participant's compliance with the terms of the IOTA Model, including this subpart.

(2) When scheduling the site visit, CMS or its designee provides, to the extent practicable, the IOTA participant with no less than 15 days advance notice of any site visit. CMS—

(i) Attempts, to the extent practicable, to accommodate a request for particular dates in scheduling site visits; and

(ii) Does not accept a date request from the IOTA participant that is more than 60 days after the date of the initial site visit notice from CMS.

(3) The IOTA participant must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(4) CMS may perform unannounced site visits at the office of the IOTA participant at any time to investigate concerns about the health or safety of attributed patients or other program integrity issues.

(5) Nothing in this part may be construed to limit or otherwise prevent

CMS from performing site visits permitted or required by applicable law.

(d) *Reopening of payment determinations.* (1) CMS may reopen an IOTA Model-specific payment determination on its own motion or at the request of the IOTA participant, within 4 years from the date of the determination, for good cause (as defined at § 405.986 of this chapter) except if there exists reliable evidence that the determination was procured by fraud or similar fault as defined at § 405.902 of this chapter. In the case of fraud or similar fault, CMS may reopen an IOTA Model specific payment determination at any time.

(2) CMS' decision regarding whether to reopen a model-specific payment determination is binding and not subject to appeal.

§ 512.464 Remedial action.

(a) *Grounds for remedial action.* CMS may impose one or more remedial actions described in paragraph (b) of this section if CMS determines that:

(1) The IOTA participant has failed to furnish 11 or more kidney transplants for patients aged 18 years or older, regardless of payer, during a PY or any baseline years.

(2) The IOTA participant or its IOTA collaborator has failed to comply with any of the terms of the IOTA Model, including this subpart.

(3) The IOTA participant has failed to comply with transparency requirements described at § 512.442.

(4) The IOTA participant or its IOTA collaborator has failed to comply with any applicable Medicare program requirement, rule, or regulation.

(5) The IOTA participant or its IOTA collaborator has taken any action that threatens the health or safety of an attributed patient.

(6) The IOTA participant or its IOTA collaborator has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model.

(7) The IOTA participant or its IOTA collaborator has undergone a change in control that presents a program integrity risk.

(8) The IOTA participant or its IOTA collaborator is subject to any sanctions of an accrediting organization or a Federal, State, or local government agency.

(9) The IOTA participant or its IOTA collaborator is subject to investigation or action by HHS (including the HHS Office of Inspector General or CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including any of the following:

(i) Being subject to the filing of a complaint or filing of a criminal charge.

(ii) Being subject to an indictment.

(iii) Being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action.

(10) The IOTA participant or its IOTA collaborator has failed to demonstrate improved performance following any remedial action imposed under this section.

(11) The IOTA participant has misused or disclosed beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

(b) *Remedial actions.* If CMS determines that one or more grounds for remedial action described in paragraph (a) of this section has taken place, CMS may take one or more of the following remedial actions:

(1) Notify the IOTA participant and, if appropriate, require the IOTA participant to notify its IOTA collaborators of the violation.

(2) Require the IOTA participant to provide additional information to CMS or its designees.

(3) Subject the IOTA participant to additional monitoring, auditing, or both.

(4) Prohibit the IOTA participant from distributing model-specific payments, as applicable.

(5) Require the IOTA participant to terminate, immediately or by a deadline specified by CMS, its sharing arrangement with an IOTA collaborator with respect to the IOTA Model.

(6) Terminate the IOTA participant from the IOTA Model.

(7) Suspend or terminate the ability of the IOTA participant to provide Part B and Part D immunosuppressive drug cost sharing support in accordance with § 512.456 or attributed patient engagement incentives in accordance with § 512.458.

(8) Require the IOTA participant to submit a corrective action plan in a form and manner and by a deadline specified by CMS.

(9) Discontinue the provision of data sharing and reports to the IOTA participant.

(10) Recoup model-specific payments.

(11) Reduce or eliminate a model-specific payment otherwise owed to the IOTA participant.

(13) Any other action as may be permitted under the terms of this part.

§ 512.466 Termination.

(a) *Termination of IOTA participant from the IOTA Model by CMS.* CMS may immediately or with advance notice terminate an IOTA participant from participation in the model if CMS does any of the following:

(1) Determines that it no longer has the funds to support the IOTA Model.

(2) Modifies or terminates the IOTA Model in accordance with section 1115A(b)(3)(B) of the Act.

(3) Determines that the IOTA participant has done any of the following:

(i) Failed to comply with any model requirements or any other Medicare program requirement, rule, or regulation.

(ii) Failed to comply with a monitoring or auditing plan or both.

(iii) Failed to submit, obtain approval for, implement or fully comply with the terms of a corrective action plan.

(iv) Failed to demonstrate improved performance following any remedial action.

(v) Taken any action that threatens the health or safety of a Medicare beneficiary or other patient.

(vi) Submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model.

(vii) Undergoes a change in control.

(viii) Assigns or purports to assign any of the rights or obligations under the IOTA Model, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.

(ix) Poses significant program integrity risks, including but not limited to—

(A) Is subject to sanctions or other actions of an accrediting organization or a Federal, State, or local government agency; or

(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 being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

(b) *Termination of Model participation by IOTA participant.* The IOTA participant may not terminate their participation in the IOTA Model.

(c) *Financial settlement upon termination.* If CMS terminates the IOTA participant's participation in the IOTA Model, CMS calculates the final performance score and any upside risk payment or downside risk payment, if applicable, for the entire PY in which the IOTA participant's participation in the model was terminated.

(1) If CMS terminates the IOTA participant's participation in the IOTA Model, CMS determines the IOTA participant's effective date of termination.

(2) If CMS terminates the IOTA participant for any reasons listed under § 512.466:

(i) CMS does not make any payments of upside risk payment for the PY in which the IOTA participant was terminated; and

(ii) The IOTA participant will remain liable for payment of any downside risk payment up to and including the PY in which termination becomes effective.

(d) *Termination of the IOTA Model by CMS.* (1) The general provisions for the Innovation Center model termination by CMS listed under § 512.165 apply to the IOTA Model.

(i) CMS may terminate the IOTA Model for reasons including, but not limited to, those set forth in § 512.165(a).

(ii) If CMS terminates the IOTA Model, CMS provides written notice to IOTA participants specifying the grounds for model termination and the effective date of such termination.

(2) In accordance with section 1115A(d)(2) of the Act and § 512.170(e), termination of the IOTA Model under section 1115A(b)(3)(B) of the Act is not subject to administrative or judicial review.

(3) If CMS terminates the IOTA Model, the financial settlement terms described in paragraph (c) of this section apply.

§ 512.468 Bankruptcy and other notifications.

(a) *Notice of bankruptcy.* (1) If the IOTA participant has filed a bankruptcy petition, whether voluntary or involuntary, the IOTA participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the IOTA participant under the terms of each model tested under section 1115A of the Act in which the IOTA participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved.

(2) The notice of bankruptcy must meet all of the following:

(i) Be sent by certified mail no later than 5 days after the petition has been filed.

(ii) Contain—

(A) A copy of the filed bankruptcy petition (including its docket number); and

(B) A list of all models tested under section 1115A of the Act in which the IOTA participant is participating or has participated.

(b) *Change in control.* (1) The IOTA participant must provide written notice to CMS at least 90 days before the effective date of any change in control.

(2) CMS may terminate an IOTA participant from the IOTA Model under § 512.466 if the IOTA participant undergoes a change in control.

(c) *Prohibition on assignment.* (1) Unless CMS provides prior written consent, an IOTA participant must not transfer, including by merger (whether the IOTA participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise any—

(i) Discretion granted it under the model;

(ii) Right that it has to satisfy a condition under the model;

(iii) Remedy that it has under the model; or

(iv) Obligation imposed on it under the model.

(2) The IOTA participant must provide CMS 90 days advance written notice of any such proposed transfer.

(3) This obligation remains in effect after the expiration or termination of the model, or the IOTA participant's participation in the model, and until final payment by the IOTA participant under the model has been made.

(4) CMS may condition its consent to such transfer on full or partial reconciliation of upside risk payments and downside risk payments.

(5) Any purported transfer in violation of this requirement is voidable at the discretion of CMS.

Waivers

§ 512.470 Waivers.

CMS waives the requirements of sections 1881(b), 1833(a) and 1833(b) of the Act only to the extent necessary to make the payments under the IOTA Model described in this subpart.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–27841 Filed 11–26–24; 4:15 pm]

BILLING CODE 4120–01–P