DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS–5535–P]

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: Proposed rule.

SUMMARY: This proposed rule describes a new mandatory Medicare payment model, the Increasing Organ Transplant Access Model (IOTA Model), that would test whether performance-based incentive 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 proposed rule also includes standard provisions that would apply to Innovation Center models whose first performance period begins on or after January 1, 2025, and also would apply, in whole or part, to any Innovation Center model whose first performance period begins prior to January 1, 2025 should such model's governing documentation incorporate the provisions by reference in whole or in part. The proposed 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: To be assured consideration, comments must be received at one of the addresses provided below, by July 16, 2024.

ADDRESSES: In commenting, please refer to file code CMS–5535–P.

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5535–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services,Department of Health and Human Services, Attention: CMS–5535–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

FOR FURTHER INFORMATION CONTACT: *CMMItransplant@cms.hhs.gov* for questions related to the Increasing Organ Transplant Access Model.

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

SUPPLEMENTARY INFORMATION:

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

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I. Executive Summary

A. Purpose

Section 1115A of the Social Security Act (the Act) gives the Secretary 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. This proposed 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 would begin on January 1, 2025 and end on December 31, 2030. In this proposed rule, we propose payment policies, participation requirements, and other provisions to test the IOTA Model. We propose 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 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 kidney transplant hospital accountability by tying payments to value. The IOTA Model is also intended to advance health equity by improving equitable access to the transplantation ecosystem through design features such as a proposed health equity plan requirement to address health outcome disparities and a health equity performance adjustment.

This proposed rule also includes proposed standard provisions that would apply to Innovation Center models whose first performance periods begin on or after January 1, 2025, unless otherwise specified in a model's governing documentation, as well as to Innovation Center models whose first performance periods begin prior to January 1, 2025, provided the standard provisions are incorporated into such models' governing documentation. The proposed 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.

We seek public comment on these proposals, the alternatives considered, and the request for information (RFI) in section III.D. of this proposed rule.

B. Summary of the Proposed Provisions

1. Standard Provisions for Innovation Center Models

The proposed standard provisions for Innovation Center models would be applicable to all Innovation Center models whose first performance periods begin on or after January 1, 2025, subject to any limitations specified in a model's governing documentation. The proposed standard provisions also would apply to all Innovation Center models whose first performance periods begin prior to January 1, 2025, provided the standard provisions are incorporated into such models' governing documentation.

We are proposing to codify these standard provisions to increase transparency, efficiency, and clarity in the operation and governance of Innovation Center models, and to avoid the need to restate the provisions in each model's governing documentation. The proposed standard provisions include terms that have been repeatedly memorialized, with minimal variation, in existing models' governing documentation. The proposed standard provisions are not intended to encompass all of the terms and conditions that would apply to each Innovation Center model, because each model embodies 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 would continue to be included in each model's governing documentation. Model-specific provisions applicable to the IOTA Model proposed herein are described in section III of this proposed 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.[1] 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.[2] For ESRD patients, regular dialysis sessions or a kidney transplant is required for survival. 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.[3] [4] However, despite these benefits, 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.[5] [6] 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). Consistent with this priority, and through joint efforts with HHS' Health Resources and Services Administration (HRSA), the proposed IOTA Model would aim to reduce Medicare expenditures and improve performance and equity in kidney transplantation by creating performance-based incentive payments for participating kidney transplant hospitals tied to access and quality of care for ESRD patients on the hospitals' waitlists.

The proposed IOTA Model would be a mandatory model that would begin on January 1, 2025 and end on December 31, 2030, resulting in a 6-year model performance period (''model performance period'') comprised of 6 individual performance years (each a ''performance year'' or ''PY''). The proposed IOTA Model would 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 would select kidney transplant hospitals to participate in the IOTA Model through the methodology proposed in section III.C.3.d of this proposed rule. As this would be a mandatory model, the selected kidney transplant hospitals would be required to participate. CMS would measure and assess the participating kidney transplant hospitals' performance during each PY across three performance domains: achievement, efficiency, and quality.

The achievement domain would 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 would assess the kidney organ offer acceptance rates of each participating kidney transplant hospital relative to the national rate. The quality domain would assess the quality of care provided by the participating kidney transplant hospitals across a set of proposed outcome metrics and quality measures. Each participating kidney transplant hospital's performance score across these three domains would determine its final performance score and corresponding amount for the performance-based incentive payment that CMS would pay to, or the payment that would be owed by, the participating kidney transplant hospital. The proposed upside risk payment would 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 after PY 2, the downside risk payment would be a lump sum payment paid to CMS by any participating kidney transplant hospital

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

[2] 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.

[3] 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: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 11*(10), 2093–2109. *https://doi.org/10.1111/j.1600-6143.2011.03686.xhttps://doi.org/10.1111/j.1600-6143.2011.03686.*

[4] 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.2022.184.*

[5] 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.*

[6] 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.2023.02.1081.*

with a final performance score of 40 or lower. We are not proposing a downside risk payment for PY 1 of the model.

b. Model Scope

We propose that participation in the IOTA Model would be mandatory for 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. As discussed in section III.C.3.b. of this proposed 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.

We propose that eligible kidney transplant hospitals would 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) furnished more than 50 percent of the hospital's annual kidney transplants to patients 18 years of age or older during that same period. We propose 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 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 proposed rule, a DSA has the same meaning given to that term at 42 CFR 486.302.

c. Performance Assessment

We propose to assess each IOTA participants' 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 would 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 would 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 would be heavily weighted on the achievement domain to align with the IOTA Model's goal to increase access to kidney transplants. 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.

We propose that CMS would 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 (the ''transplant target''), as described in section III.C.5.c of this proposed rule. Each IOTA participant's transplant target for a given PY would 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 and further adjusted by the proportion of transplants furnished by the IOTA participant to attributed patients who are low income. Section III.C.5.c. of this proposed 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 would 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 because of the way in which the transplant target would be calculated.

The efficiency domain would 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. Points for the kidney organ offer acceptance rate ratio would be determined 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 performance on the efficiency domain being worth up to 20 points.

Finally, the quality domain would assess IOTA participants' performance on post-transplant outcomes in addition to three quality measures—the CollaboRATE Shared Decision-Making Score, Colorectal Cancer Screening, and the 3-Item Care Transition Measure, with performance on this domain being worth up to 20 points.

Each IOTA participant's final performance score would be the sum of the points earned for each domain: achievement, efficiency, and quality. The final performance score in a PY would be determinative of whether the IOTA participant would 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 proposed rule.

d. Performance-Based Incentive Payment Formula

Each IOTA participant's final performance score would determine whether: (1) CMS would pay an upside risk payment to the IOTA participant; (2) the IOTA participant would fall into a neutral zone, in which case no performance-based incentive payment would be paid to or owed by the IOTA participant; or (3) the IOTA participant would owe a downside risk payment to CMS. For a final performance score above 60, CMS would apply the formula for the upside risk payment, which we propose would be equal to the IOTA participant's final performance score minus 60, then divided by 60, then multiplied by $8,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to attributed patients with Medicare 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 in PYs 2–6 would fall in the neutral zone where there would be no payment owed to the IOTA participant or CMS.

We propose to phase-in the downside risk payment beginning in PY2. We explain in section III.C.5.b. of this proposed 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 proposes an upside risk-only approach for PY 1 as an incentive in each of the three performance domains. This would give IOTA participants time to consider, invest in, and implement value-based care and quality improvement initiatives before downside risk payments would begin. Beginning in PY 2, for a final performance score of 40 and below, CMS would apply the formula for the downside risk payment, which would be equal to the IOTA participant's final performance score minus 40, 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 as their primary or secondary payer during the PY.

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

risk payment to CMS in a lump sum after the PY.

e. Data Sharing

We propose to 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 would also share certain data with IOTA participants upon request as described in section III.C.3.a. of this proposed rule and as permitted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and other applicable law. We propose to 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 would be allowed only to the extent permitted by the HIPAA Privacy Rule and other applicable law and CMS policies. We also propose to share certain aggregate, de-identified data with IOTA participants.

f. Other Requirements

We propose several other model requirements for selected transplant hospitals, including transparency requirements, public reporting requirements, and a health equity plan requirement which would be optional for PY1 and required for PY 2 through PY 6, as described in section III.C.8. of this proposed rule.

(1) Transparency Requirements

Patients are often unsure whether they qualify for a kidney transplant at a given kidney transplant hospital. We propose that IOTA participants would 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. We also propose to add requirements to facilitate increased transparency for patients regarding the organ offers received on the patient's behalf while the patient is on the waitlist. Specifically, we propose that IOTA participants would be required to inform patients on the waitlist, on a monthly basis, of the number of times an organ was declined on each patient's behalf and the reason(s) why each organ was declined. We believe that notifying patients of the organs declined on their behalf would encourage conversations between patients and their providers regarding a patient's preferences for transplant and facilitate better shared decision-making.

(2) Health Equity Requirements

We propose that during the model's first PY, each IOTA participant would have the option to submit a health equity plan (''HEP'') to CMS. We propose that each IOTA participant would then be required to submit a HEP to CMS for PY 2 and to update its HEP for each subsequent PY. We propose that the IOTA participant's HEP would identify health disparities within the IOTA participant's population of attributed patients and outline a course of action to address them.

We also considered proposing to require IOTA participants to collect and report patient-level health equity data to CMS. Specifically, we considered proposing that IOTA participants would be required to conduct health related social needs screening for at least three core areas—food security, housing, and transportation. We recognize these areas as some of the most common barriers to kidney transplantation and the most pertinent health related social needs for the IOTA patient population.[7] We have included an RFI in this proposed rule to solicit feedback and comment on such a requirement.

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 propose to issue these waivers using our waiver authority under section 1115A(d)(1) of the Act. Each of the proposed waivers is discussed in detail in section III.C.10. of this proposed 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 would participate in multiple Innovation Center models. We believe that the IOTA Model would be compatible with existing models and programs that provide opportunities to improve care and reduce spending. The IOTA Model would 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 proposes performance-based payments separate from what participants would be paid by CMS for furnishing kidney transplants to Medicare beneficiaries. Additionally, we would 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 propose to allow overlaps between the IOTA Model and other Innovation Center models and CMS programs.

i. Monitoring

We propose to closely monitor the implementation and outcomes of the IOTA Model throughout its duration consistent with the monitoring requirements proposed in the Standard Provisions for Innovation Center models in section II of this proposed rule and the proposed requirements in section III.C.13. of this proposed rule. The purpose of this monitoring would 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 proposed in section III.C.10. of this proposed rule, CMS would not allow beneficiaries or patients to opt out of attribution to an IOTA participant; however, the IOTA Model would not restrict a beneficiary's freedom to choose another kidney transplant hospital, or any other provider or supplier for healthcare services, and IOTA participants would be subject to the Standard Provisions for Innovation Center Models outlined in section II. of this proposed rule protecting Medicare beneficiary freedom of choice and access to medically necessary services. We also would 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. Additionally, IOTA participants would be subject to the proposed Standard Provisions for Innovation Center Models regarding descriptive model materials and activities in section II. of this proposed rule.

[7] Venkataraman, S., & Kendrick, J. (2020). Barriers to kidney transplantation in ESKD. *Seminars in Dialysis, 33*(6), 523–532. *https://doi.org/10.1111/sdi.12921.*

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. There is reasonable evidence that the savings to Medicare resulting from an incremental growth in transplantation would potentially exceed the payments projected under the model's proposed 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 expected to reduce Medicare, Medicaid, and CHIP expenditures, while preserving or enhancing the quality of care furnished to such programs' beneficiaries. We have designed and tested both voluntary Innovation Center models—governed by participation agreements, cooperative agreements, and model-specific addenda to existing contracts with CMS—and mandatory Innovation Center models that are governed by regulations. Each voluntary and mandatory model features its own specific payment methodology, quality metrics, and certain other applicable policies, but each model also features numerous provisions of a similar or identical nature, including provisions regarding cooperation in model evaluation; monitoring and compliance; and beneficiary protections.

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.[8] 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, we now believe the general provisions should apply to Innovation Center models more broadly. As we note, the Innovation Center models share numerous similar provisions, and codifying the general provisions into law to expand their applicability across models, except where otherwise explicitly specified in a model's governing documentation, would, we believe, 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 propose 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 believe that 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 propose 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 propose 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

[8] 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 part 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.

above. We propose specific revisions that would be necessary to expand the scope of several of the current general provisions, but otherwise propose that the general provisions (which would be referred to as the ''standard provisions for Innovation Center models'') would not change. In particular, we propose 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. Proposed Revisions to the Titles, Basis and Scope Provision, and Effective Date

We propose 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 closely aligns with the other changes proposed herein 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 propose to amend the title of subpart A to read ''Standard Provisions for Innovation Center Models'' to use the term we propose to define the provisions codified at 42 CFR part 512 subpart A.

Additionally, we propose 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 propose 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 believe that these standard provisions are necessary for the testing of the IOTA model, regardless of whether they are finalized as proposed for all Innovation Center models. As such, as an alternative to the previous proposal, we would propose 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.

These proposed standard provisions would not, except as specifically noted in this section II. of this proposed rule, affect the applicability of other provisions affecting providers and suppliers under Medicare fee-for-service (FFS).

We invite public comment on these proposed changes.

D. Provisions Revising Certain Definitions

We propose 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 propose 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 propose 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 propose to add a new definition, ''standard provisions for Innovation Center models,'' at § 512.110 to mean, ''the provisions codified in 42 CFR 512 Subpart A.'' We propose 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 propose to amend the definitions of ''Innovation Center model activities,'' ''model beneficiary,'' and ''model participant'' to pertain to all ''Innovation Center models,'' as we propose to define that term, instead of just the models previously implemented under part 512. As such, we propose 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 propose to define ''model beneficiary'' to mean ''a beneficiary attributed to a model participant or otherwise included in an Innovation Center model.'' We propose to define ''model participant'' to mean ''an individual or entity that is identified as a participant in the Innovation Center model.''

We invite 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.''

E. Proposed Reconsideration Review Process

We propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose that requests that do not meet the requirements of paragraph (b)(1) would be denied.

We propose 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 propose 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 propose that the reconsideration review process would not be available to the model participant with regard to that model-specific payment.

We propose to codify standards for reconsideration at § 512.190(c). First, during the course of the reconsideration, we propose 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 propose 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 propose 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 propose 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 propose to codify at § 512.190(e) a process for the CMS Administrator to review reconsideration determinations made under § 512.190(d). We propose 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 invite public comment on the proposed reconsideration review process for Innovation Center models.

III. Proposed Increasing Organ Transplant Access (IOTA) Model

A. Introduction

In this proposed rule, we are proposing to test the IOTA Model, a new mandatory Medicare alternative payment model under the authority of the Innovation Center, that would begin on January 1, 2025, and end on December 31, 2030. The IOTA Model would test whether using performance-based incentive payments in the form of upside risk payments and downside risk payments to and from select transplant hospitals 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 proposed 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 medical and non-medical needs of patients; and increased awareness, education, and support for living donations. The IOTA Model payment structure would 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 would reduce Medicare expenditures by reducing dialysis expenditures and avoidable health care service utilization and would improve the quality of life for patients with ESRD.

As discussed in section III.B of this proposed 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.[9] 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 or hold them financially accountable for not doing so. The IOTA Model's proposed payment structure would include upside or 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''), with these payments being tied to performance on achievement, efficiency, and quality domains.

The achievement domain would 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 would 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, with performance on this domain being worth up to 20 points. The quality domain would assess performance based on post-transplant outcomes at one-year after transplant and a proposed set of quality measures, with performance on this domain being worth up to 20 points. The achievement domain would be weighted more heavily than the other two domains because increasing the number of transplants is a key goal of the model and would be a primary factor in determining the amount of the performance-based payment.

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

- 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(a) of this proposed rule (final performance score minus 60, then divided by 60, then multiplied by $8,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to beneficiaries with Medicare 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 qualify for the downside risk payment in accordance with the proposed calculation methodology described in section III.C.6.c.(b). of this proposed rule (final performance score minus 40, 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 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 proposed 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 would 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 proposed payment methodology would act in concert with measures that are currently under development by HRSA to increase the numbers of both deceased and living donor organ transplants.

This proposed 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.[10]

[9] 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.*

[10] Moody-Williams, J.D., & Nair, S. (2023, September 15). Organ Transplantation Affinity

Continued

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.[11] 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.[12] 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.[13] 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.[14] The IOTA Model proposes 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 propose the IOTA Model as a complement to wider efforts aimed at transplant ecosystem performance and equity improvements. Ultimately, we seek a set of interventions that focus on ESRD patients in need of a kidney transplant. In this section of the proposed rule, we summarize the transplant ecosystem and HHS oversight within CMS and HRSA related to kidney transplantation, highlight related initiatives and priorities nationally, and outline 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.[15] 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 coordinates the nation's organ procurement, distribution, and transplantation systems. The OPTN is a network of clinical experts, patients, donor families, and community stakeholders who work collectively to develop, implement, and monitor organ allocation policy and performance of the organ transplant ecosystem.

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 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 to have its costs reimbursed by the Secretary. 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, donor and beneficiary evaluation, and living donor complications. 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

Group (OTAG): Strengthening accountability, equity, and performance √ CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

[11] 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.*

[12] 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.*

[13] 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.*

[14] 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.*

[15] 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.*

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, 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.[16] 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.[17]

Once placed on the waitlist, potential recipients must maintain active status to be eligible to receive a deceased donor transplant.[18] 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'.[19] 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.[20] [21] 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.[22]

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.[23] 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 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.[24]

CMS oversees and evaluates OPO performance. OPOs must meet performance measures and participate in, and abide by certain rules of, the OPTN.[25] 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, the OPTN Bylaws 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).[26] 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 organ acquisition costs including kidney registry fees and laboratory tests associated with the evaluation of a Medicare transplant candidate. The evaluation or preparation of a living 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. 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

[16] 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.*

[17] 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.*

[18] 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.*

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

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

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

[22] *Transplant Nephrology Fellowship.* (n.d.). *Www.hopkinsmedicine.org.* Retrieved May 30, 2023, from *https://www.hopkinsmedicine.org/nephrology/education/transplant_fellowship.html#:~:text=Diagnose%20and%20manage%20acute%20and.*

[23] 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. HRSA also intends to issue contract solicitations for multiple awards to support the OPTN.

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

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

[26] Bylaws—OPTN. (n.d.). Optn. *transplant.hrsa.gov.* Retrieved May 30, 2023, from *https://optn.transplant.hrsa.gov/policies-bylaws/bylaws/.*

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 51749). 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.[27]

While these regulatory changes recently 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.[28] [29] In particular, we recognize that further action must be taken to address disparities and inequities observed across transplant hospitals.

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

[27] 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.*

[28] One study—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*—showed that deceased donor organ donation increased during 2019, that is., during the period of public debate about regulating OPO performance.

[29] 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).

• 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.[30] 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 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).

CMS is also operating the ETC Learning Collaborative, which is focused on increasing the availability of deceased donor organs for transplantation.[31] 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

[30] 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.

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

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.[32]

The IOTA Model proposes to complement the ETC and KCC Models 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.

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.[33] 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.[34] 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 the OPTN Bylaws 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: [35]

- 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 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 the OPTN Bylaws, 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 Centers of Excellence 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.[36] Strengthening and improving the

[32] The evaluation report for the first two years (2021, 2022) of the ETC Model is available at *https://www.cms.gov/priorities/innovation/data-reports.*

[33] *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.*

[34] 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/#:~:text=On%20Friday%2C%20September%2022%2C%202023,Organ%20Procurement%20and%20Transplantation%20Network.*

[35] OPTN. (n.d.). *Enhance Transplant Program Performance Monitoring System, Phase 1 (July 2022) Sponsoring Committee: Membership and Professional Standards Bylaws Affected.* Retrieved August 20, 2023, from *https://optn.transplant.hrsa.gov/media/hgkksfuu/phase-1_tx-prgm-performance-monitoring_dec-2021.pdf.*

[36] 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.*

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.'' [37] Collectively, CMS and HRSA seek to—

- Reduce variation of pre-transplant and referral practices; [38]
- 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.

We believe the proposed 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, as proposed, 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. Furthermore, although we are targeting our proposals to kidney transplant programs, we seek to test specific modifications for Medicare payment and other programmatic measures that would establish a framework for potential future interventions for transplantation relating to the other solid organ types.

In the following sections of this proposed rule, we review scientific literature that outlines specific ways that kidney transplantation can be enhanced. Although not the focus of our analysis, we also present findings pertaining to the transplantation of other organs, especially livers. We aim to show how the types of interventions that we are proposing 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 our proposals to use payment incentives as a policy lever to increase the number of kidney transplants and achieve a fairer distribution.

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.[39] Prevalence of ESRD varied by Health Service Area (HSA) and ESRD Network.[40] Stratified by age and race/ethnicity, ESRD was consistently more prevalent among older people (65 and older) and in Black people.[41] Diabetes and hypertension are most often the primary cause of ESRD.[42] According to the National Kidney Foundation, these diseases disproportionately affect minority populations, increasing the risk of kidney disease.[43] 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.[44] Studies show that people with kidney transplants live longer than those who remain on dialysis.[45] 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.[46] In 2021, 72,864 patients with ESRD were on the kidney transplant waitlist, of which 27,413 were listed during that year.[47] The IOTA Model proposes to 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.[48]

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 proposes 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.[49] 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.[50] The kidney in such

[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] 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.

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

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

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

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

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

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

[45] National Kidney Foundation. (2017, February 14). *Kidney Transplant.* National Kidney Foundation. *https://www.kidney.org/atoz/content/kidney-transplant.*

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

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

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

[49] 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/.*

[50] Health Resources and Services Administration. (2020). Scientific Registry for Transplant Recipients. *OPTN/SRTR 2020 Annual Data Report:*

Continued

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.[51] 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 numbers of deceased donor kidney donation have increased over the past decade, while living donor kidney donation has remained relatively constant, declining in 2020 with the COVID–19 pandemic.[52]

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.[53] According to one source, the majority of deceased donor kidneys are expected to function for about 9 years, with high quality organs lasting longer.[54] A systematic review of studies worldwide finds significantly lower mortality and risk of cardiovascular events associated with kidney transplantation compared with dialysis.[55] Additionally, this review finds that patients who receive transplants experience a better quality of life than treatment with dialysis.[56] 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.[57] Among transplant recipients, there are lower rates of hospitalizations, emergency department visits, and readmissions compared to those still on dialysis.[58] 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.[59] [60]

A cost advantage also arises with kidney transplantation. Per person per year Medicare FFS spending for beneficiaries with ESRD with a transplant is less than half that for either hemodialysis or peritoneal dialysis.[61] 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.[62] 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.[63]

Despite these outcomes, 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.[64] In 2016, only 2.8 percent of incident ESRD patients—meaning patients newly diagnosed with ESRD—received a preemptive kidney transplant, allowing them to avoid dialysis.[65] 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.[66] 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.[67] 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.[68] [69] [70] These trends have persisted

Pancreas. https://srtr.transplant.hrsa.gov/annual_reports/2020/Pancreas.aspx.

[51] 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.

[52] 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.

[53] *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.*

[54] 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/#:~:text=Figure%201%20shows%20that%20a,function%20for%20about%209%20years.*

[55] 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.*

[56] Ibid.

[57] 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.

[58] 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.

[59] 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.*

[60] 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.

[61] 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.

[62] 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.*

[63] 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.*

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

[65] 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.usrds.org/2018/view/v2_01.aspx.*

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

[67] 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.

[68] Scientific Registry of Transplant Recipients. Program Specific Reports. *Www.srtr.org.* Retrieved

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.[71] [72] In 2018 and 2019, the total number of kidney transplants rose steadily as compared to previous years.[73] 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.[74] 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.[75] 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.[76] 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.[77] At the end of 2021, 72,864 individuals were on the waitlist for a kidney transplant.[78]

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.[79] [80] 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.[81] 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.[82] A study in 2013 of OPTN data found that the decline in living donation 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.[83]

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.[84] [85] [86] [87] [88] Studies during the past decade have shown substantial disparities in kidney transplant rates among transplant programs at a national level, as well as both among and within donation service areas (DSAs).[89] A 2020 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.[90] 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.[91] 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

June 15, 2023, from *https://www.srtr.org/reports/program-specific-reports/*.

[69] 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.*

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

[71] 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.*

[72] 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.*

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

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

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

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

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

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

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

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

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

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

[83] 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.*

[84] 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.*

[85] 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).

[86] United States Renal Data System. 2022. Annual Data Report. Supplements: COVID–19, Racial and Ethnic Disparities Figures 14–4 and 14.15.

[87] 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.*

[88] 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.*

[89] With the enactment of NOTA, CMS designated donation service areas (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.

[90] 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.*

[91] King et al. 2020. 2903.

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.[92] 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.[93] 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.[94] 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.[95] 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.[96]

The literature over several decades has also addressed the effect of differences in age, gender, socioeconomic status (SES), and cultural aspects.[97] 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.[98] [99] [100] [101] This 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.[102] 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.[103] As described in recent literature, a person's SDOH may contribute to inequities in their prospects for waitlist registration and receipt of transplantation.[104] [105] [106] 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.[107] More specifically, SDOH include variations in employment, neighborhood factors, education, social support systems, and healthcare coverage that impact health outcomes.

Salient among recent analyses are those of 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. However, after the introduction of the KAS in 2014, racial difference showed weaker associations with rates of waitlist registration and receipt of a deceased donor transplant, when controlling for SDOH.[108] [109] This finding is consistent with reports showing a decrease nationally in differences in rates of deceased donor kidney transplants among White patients as compared to Black/African American patients and Hispanic/Latino patients on dialysis, following the introduction of the KAS.[110] [111] The studies of this patient cohort showed Black/African American race to be associated with a decrease in probability of kidney transplant, while still according influence to clinical, social, demographic and cultural factors. These factors included older age, lower income, public insurance, having more comorbidities, being transplanted pre-KAS, less social support, and less transplant knowledge.[112] Similarly, an earlier study of a population at a single

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

[93] King et al. 2020. 2903–2904.

[94] 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).

[95] United States Renal Data System. 2022. Annual Data Report. Supplements: COVID–19, Racial and Ethnic Disparities Figures 14–4 and 14.15.

[96] National Kidney Foundation. (2016, January 7). Race, Ethnicity, & Kidney Disease. National Kidney Foundation. *https://www.kidney.org/atoz/content/minorities-KD#:~:text=Black%20or%20African%20Americans%20are.*

[97] 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.*

[98] 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.*

[99] 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.*

[100] 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.*

[101] 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.*

[102] 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. *https://doi.org/10.1097/tp.0000000000003003.*

[103] National Academies of Science, Engineering, and Medicine. 2022. ''Realizing the Promise of Equity in the Organ Transplantation System. National Academies Press. Washington DC. 88–93.

[104] Centers for Disease Control and Prevention. *Social Determinants of Health at CDC.* Retrieved June 13, 2023, from *https://www.cdc.gov/about/sdoh/index.html.*

[105] Wesselman et al., 2021.

[106] Ng et al., 2020.

[107] Centers for Disease Control and Prevention.

[108] Ng Y et al. 2020. 8.

[109] Wesselman et al., 2021. 271.

[110] United States Renal Data System. 2022. Annual Data Report. End Stage Renal Disease Chapter 7 Transplantation. Figures 7.10a, 7.10b.

[111] *OPTN Two Year Analysis shows effects of Kidney Allocation System https://optn.transplant.hrsa.gov/news/two-year-analysis-shows-effects-of-kidney-allocation-system/.*

[112] Wesselman et al. 2021. 267.

transplant hospital found that socioeconomic factors attenuated the association between racial difference and placement on the waitlist for a kidney transplant.[113] This underscores 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 for deceased donor donation.[114] 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.[115] 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.[116] [117]

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.[118] [119] [120] [121] 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).[122] 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.[123]

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 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.[124] 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.[125]

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.[126] 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.[127] 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.[128]

CMS has kept these concerns in mind when developing the IOTA Model proposals. The IOTA Model proposes 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 is proposing that the IOTA participants would be required to develop and submit a Health Equity Plan to CMS in PYs 2 through 6. This proposed 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. Thus, we believe that a unified framework of interventions to address the distinct social contexts underlying differences among racial groups in deceased donor kidney transplantation and living donor kidney transplantation may result in the desired outcomes of greater overall kidney transplant numbers and equity.

[113] Schold et al., 2021.

[114] Wesselman et al., 2021. 270.

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

[116] 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.*

[117] 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.*

[118] 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.*

[119] 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.*

[120] 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.*

[121] Rodrigue et al. 2015.

[122] Purnell et al. 2015. 58.

[123] Purnell et al. 2015. 59.

[124] Hall et al. 2012. 855.

[125] Hall et al. 2012. 855.

[126] *See, for example.,* Nat'l Council on Disability, Organ Transplants Discrimination against People with Disabilities: Part of the Bioethics and Disability Series (2019), *https://ncd.gov/sites/default/files/NCD_Organ_Transplant_508.pdf.*

[127] *Id.* at 38–40.

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

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.[129] 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.[130] 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.[131] 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).[132]

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.[133] 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.[134]

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.[135] [136] [137] [138] [139] 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 in non-utilization.[140] 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.[141] [142] An analysis found that the donor kidney discard rate peaked at 27 percent during the fourth quarter of 2021.[143]

Since 2014, when the KAS went into effect, 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.[144] The KAS also revised the system that matched waitlisted individuals with available organs.[145] 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.[146] 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

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

[130] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figures 7.20a and 720.b.

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

[132] United States Renal Data System. 2023. Annual Data Report Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 721.b.

[133] Hariharan S, Israni AK, Danovitch G. Long-Term Survival after Kidney Transplantation. N Engl J Med. 2021 Aug 19;385(8):729–743. doi: 10.1056/NEJMra2014530. PMID: 34407344.

[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] 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.*

[136] 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.*

[137] 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.*

[138] 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.*

[139] 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/.*

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

[141] 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.

[142] Following upon 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.*

[143] 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.*

[144] 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.

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

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

scores are associated with a worse expected outcome in this regard.[147]

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.[148]

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.[149] 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.[150]

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.[151] [152] 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.[153]

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.[154] 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.[155] [156] [157] 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 geographic areas.[158] Another report cited unpublished SRTR data, saying that preliminary results suggest an increase in transplant rate overall, but a trend toward higher donor kidney discard and increased cold ischemia time.[159] A study at a single transplant hospital showed that the number of organ offers—for livers and kidneys—grew by 140 percent between May 1, 2019, and July 31, 2021, while the number of transplanted organs remained stable, suggesting less efficient allocation of organs after the new change in allocation policy.[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

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

[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. (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/.*

[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] 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.*

[152] 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.*

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

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

[155] 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.*

[156] 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.*

[157] 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.*

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

[159] 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.*

[160] Reddy, V., Briget da Graca, Martinez, E., Ruiz, R., Asrani, S.K., Testa, G., & Wall, A. (2022). Single-center analysis of organ offers and workload for liver and kidney allocation. *American Journal of Transplantation, 22*(11), 2661–2667. *https://doi.org/10.1111/ajt.17144.*

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

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

[163] Mohan et al. 2018. 192.

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 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 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 on the part of transplant programs to 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 we propose for kidney transplantation, understanding and addressing why livers, and possibly other organs, are not chosen for specific patients also has the

[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 ''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.*

potential to lead to improved outcomes and longer lives.

i. Organ Transplant Affinity Group

On September 15, 2023, CMS published a blog post entitled ''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 proposed 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 Proposed Regulation

1. Proposal To Implement the IOTA Model

In this section of the proposed rule, we propose our policies for the IOTA Model, including model-specific definitions and the general framework for implementation of the IOTA Model. The proposed upside risk payment to the IOTA participants and the proposed downside risk payment from IOTA participants 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 proposed rule, access to kidney transplants widely varies by region and across transplant hospitals and disparities by demographic characteristics are pervasive, raising the need to strengthen and improve performance. We theorize that the IOTA Model financial structure would promote improvement activities across selected transplant hospitals that address access barriers, including SDOH, thereby increasing the number of transplants, quality of care, and 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 may also require 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. Proposal for Model Performance Period

We are proposing a 6-year ''model performance period.'' We are proposing to define the model performance period as the 72-month period from the model start date, comprised of 6 individual PYs. During the model performance period, the IOTA participants' performance would be measured and assessed for purposes of determining their performance-based payments, as proposed in this rule. We propose to define the ''performance year'' (PY) as a 12-month calendar year during the model performance period. We are proposing to define the start of the model performance period as the ''model start date,'' and we propose 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 are proposing 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 III.D. of this proposed rule project that considerable savings to Medicare would be achieved after the fifth PY, which is another reason why we are proposing 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 would be a mandatory model, we believe it 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 periods with that of our data sources, as detailed in section III.C. of this proposed rule. However, we are proposing a January 1, 2025 start date because we believe that there will be sufficient time for IOTA participants to prepare for the model. A proposed start date of January 1st also aligns with other CMS calendar year rules. We propose 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 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 April 1, 2025, ''performance year'' would still 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 end date would also shift to include a 72-month period from the model start date In the previous example, the model performance period would be April 1, 2025, to March 31, 2031.

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

b. Other Proposals

We are also proposing 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 propose 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 proposed revisions in this proposed rule. As described in section II.B. of this proposed rule, we are proposing 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 believe that this approach would promote transparency, efficiency, and clarity in Innovation Center models and avoid the need to restate the provisions in each

[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.*

model's governing documentation. We believe that applying these provisions to the IOTA Model would promote these purposes.

We seek 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.

2. Definitions

We propose at § 512.402 to define certain terms for the IOTA Model. We describe these proposed definitions in context throughout section III. of this proposed rule. We propose to codify the definitions and policies of the IOTA Model at 42 CFR part 512 subpart D (proposed §§ 512.400 through 512.460). In addition, we propose 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 this notice of proposed rulemaking, would also apply to the IOTA Model. We seek comment on these proposed definitions for the IOTA Model.

3. IOTA Participants

a. Proposed Participants

We propose 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 note that the definition of ''model participant'' contained in *42 CFR part 512.110,* as well as the proposed revisions to that definition, would include an IOTA participant.

We propose to define ''transplant hospital'' as a hospital that furnishes organ transplants as defined in 42 CFR 121.2. We propose this definition to align with the definition used by Medicare. We propose to define ''kidney transplant hospital'' as a transplant hospital with a Medicare approved kidney transplant program. Under § 482.70, a transplant program is ''an organ-specific transplant program within a transplant hospital (as defined in this section).'' 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 propose this definition of kidney transplant hospital to refer specifically to transplant hospitals that perform kidney transplants. We propose 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.4.b. of this 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.

Kidney transplant hospitals are the focus of the proposed IOTA Model because they are the entities that furnish kidney transplants to ESRD patients on the waitlist 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 proposed model is intended to promote improvement activities across selected transplant hospitals that reduce access barriers, including SDOH, thereby increasing the number of transplants, quality of care, and cost-effective treatment. The IOTA Model would also aim to improve quality of care for ESRD patients on the waitlist pre-transplant, during transplant, and during post-transplant care. As described in section III.B.4.e. of this proposed 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 possibly would 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 believe that the ''IOTA participant'' should be defined 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. However, in 2020, CMS issued a final rule that updated OPO CfC requirements to receive Medicare and Medicaid payment. 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.

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

b. Proposed Mandatory Participation

We propose that all kidney transplant hospitals that meet the eligibility requirements as discussed in section III.C.3.c. of this proposed rule, and that are selected through the participation selection process discussed in section III.C.3.d. of this proposed rule, must 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.

Nationally, kidney transplant hospitals serve diverse patient populations, operate in varied organizational and market contexts, and differ in size, staffing, and capability. 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 believe that selection bias would be a challenge in a voluntary model because we are proposing that the IOTA Model would include financial accountability on performance on access to kidney transplants and quality of care, and downside risk for poor performers. A mandatory model would address these selection bias concerns and ensure that our model reaches ESRD patients residing in underserved communities.

We alternatively considered making participation in the IOTA Model voluntary. However, we would be 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 reflect our expectation that the proposed payment approach 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. This may be especially true for kidney transplant hospitals that would stand the most to benefit from a model that rewards an increase in the number of kidney transplants. We believe 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 propose that the IOTA Model would be mandatory for all eligible kidney transplant hospitals selected for participation in the model, as we believe this would minimize the risk of potential distortions in the model's effects on outcomes resulting from hospital self-selection.

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

c. Participant Eligibility

We are proposing 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 proposed 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 are proposing that eligible kidney transplant hospitals would be those that: (1) performed 11 or more transplants for patients aged 18 years or older annually, regardless of payer type, each of the baseline years (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 propose 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 baseline years for PY 1 would be the 12-month period that begins January 1, 2021, and ends on December 31, 2023. We propose 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.

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 this proposed rule) would exclude low volume kidney transplant hospitals from the IOTA Model. We believe 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 are 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 have 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 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 seek 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 seek 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 seek comment on the proposal to include only kidney transplant hospitals that meet the proposed definition for a non-pediatric facility during the baseline years.

d. Participant Selection

(1) Overview and Process for Participant Selection

We propose to select eligible kidney transplant hospitals for participation in the IOTA Model using a stratified sampling of approximately half of all DSAs nationwide. All kidney transplant hospitals that meet the proposed participant eligibility criteria described in section III.C.3.c. of this 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 are currently 56 DSAs as of January 1, 2024. A map of the DSAs can be found on the SRTR website.[181] 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 propose 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 propose 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 propose using this variable to stratify the DSAs into groups because increasing the total number of adult kidney transplants is the primary metric that we propose 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.[182] 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 are proposing 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 this 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 (2021–2023) 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 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

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

[182] 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://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/*).

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 transplant hospitals located within the selected DSAs would be required to participate in the IOTA Model.

We propose 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 proposed rule, we are proposing 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 proposed rule.

(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. 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. 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's 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. 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. 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's 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.

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. If this were to occur, we would address the selection of new participants in future rulemaking.

We seek 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.

4. Patient Population and Attribution

a. Proposed Attributed Patient Population

We propose 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 proposed 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 proposed 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 proposed 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 propose 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 propose 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 propose 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 propose 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 is proposing 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 proposed 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.5. of this proposed 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. of this proposed 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 are proposing 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 seek 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 seek 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.

b. Patient Attribution Process

As described in section III.C.4.a. of this proposed rule, we propose 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 propose to define

''attributed patient'' as an IOTA waitlist patient or an IOTA transplant patient, as described in section III.C.4.a. of this proposed rule. We propose that a patient may not opt out of attribution to an IOTA participant under the model.

Section III.C.4.b.(1). of this proposed 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 propose to attribute patients to IOTA participants through an initial attribution process described in section III.C.4.b.(2). of this proposed rule; quarterly attribution would be conducted thereafter to update the patient attribution list as described in section III.C.4.b.(3). of this proposed rule, to include the dates in which patient attribution changes occur. After the fourth quarter of each PY, we propose 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 proposed rule. We propose 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 proposed 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 propose to identify kidney waitlist patients and kidney transplant patients using SRTR data, OPTN data, Medicare claims data, and Medicare administrative data.

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

(1) Attribution and De-attribution Criteria

(i) IOTA Waitlist Patient Attribution

We propose 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 propose 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 proposed rule.

As described in section III.C.4.b.(1). of this proposed rule, a kidney transplant waitlist patient may be registered to more than one waitlist, which is why we propose 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 proposed rule, we are only proposing to include non-pediatric facilities as eligible participants in the IOTA Model. In alignment with this proposal, we propose 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 and are more likely to receive a kidney transplant than adults over the age of 18. Pediatric patients under 18 years of age are also more likely to receive a living donor transplant than adults over the age of 18, and are infrequently the recipient of organs at high risk for non-use.[183] Thus, CMS is not proposing 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

[183] 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.*

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 are proposing to limit IOTA waitlist patient attribution to patients who are alive at the time of attribution.

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

(ii) IOTA Transplant Patient Attribution

We propose 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 proposed 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 proposed rule.

We propose 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 propose 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 proposed rule.

We seek comments on 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. We also seek comment on the alternative considered.

(iii) De-Attribution Criteria

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

(2) Initial Attribution

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

(3) Quarterly Attribution

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

(4) Annual Attribution Reconciliation

We propose that after the end of each PY, CMS would conduct annual attribution reconciliation. We propose 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 propose 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 proposed 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 II.C.4.b.(1).(iii). of this proposed rule, from the IOTA participant, as described in section III.C.4.b.(1).(iii). of this proposed 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 propose 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 seek comment on our proposal to conduct annual attribution reconciliation.

c. IOTA Patient Attribution Lists

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

We seek comment on our proposed attribution list policies.

5. Performance Assessment

a. Goals and Proposed Data Sources

As described in section III.B. of this 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.[184]

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.[185] 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.[186] 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.[187]

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

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

[185] Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction. **Federal Register**. *https://www.federalregister.gov/d/2018-19599/p-215.*

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

[187] *Ibid.*

IOTA participants in the model, thereby reducing Medicare program expenditures while preserving or enhancing quality of care. For the IOTA Model, we are proposing 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 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.

We propose 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 solicit comment on our proposal for selecting performance metrics and performance domains. We also solicit 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 proposed rule.

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 this proposed rule, we propose to assess performance across three domains: (1) achievement domain; (2) efficiency domain; and (3) quality domain. We propose to use one or more metrics within each domain to assess IOTA participant performance. We propose 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 propose 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 propose that the combined sum of total possible points would determine whether and how the IOTA Model performance-based payments, as described in section III.C.6.c. of this proposed rule, would apply and be calculated. We propose 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 this 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.
- The quality domain would make up 20 of 100 maximum points. As described in section III.C.5.e. of this 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 believe 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 are proposing 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 believe 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 believe this methodology for assessing performance could be applied with minimal adaptation to future IOTA participants if CMS adds other types of organs transplants to the model through rulemaking. We believe that the approach of awarding points in the achievement, efficiency, and quality domains for a score out of 100 points represents the best combination of flexibility and comparability that would allow us to assess participant performance in the IOTA Model.

The proposed performance domains and scoring structure would also allow us to combine more possible metric types within a single framework. We believe 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.

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 believe 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.

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 believe 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.

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 section III.C.5.d. and e. of this proposed rule, which we believe to be important goals of the model. Thus, we are not proposing this method to assess IOTA participant performance.

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 section III.C.5.c., d., and e. of this proposed rule.

We are soliciting 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 are also seeking 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 invite feedback on the alternatives considered.

c. Achievement Domain

As stated in section III.C.5.b. of this proposed rule, we propose measuring IOTA participant performance across three domains, one of which is the achievement domain. We propose 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 proposed rule, during a PY. We propose 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 proposed rule.

We propose 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 believe would be possible via care delivery transformation and improvement activities, including donor acceptance process improvements to reduce underutilization and discards of donor kidneys. We believe IOTA participants may also increase the number of kidney transplants furnished to patients by improving or implementing greater education and support for living donors.

We considered constructing and using a transplant waitlisting rate measure or using SRTR's transplant rate [188] 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.[189] Research also suggests 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.[190] However, for the IOTA Model, we propose 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

[188] 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*.

[189] 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*.

[190] 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*.

receipt of a kidney transplant, not 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 believe 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 seek comment on our proposed achievement domain performance metric and alternative methodologies considered for assessing transplant rates.

(1) Calculation of Transplant Target

We propose 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 propose 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 section III.C.5.c. of this proposed rule. We propose 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 propose 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 in section III.C.3.c. of this proposed 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 believe 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 understand that living donation and deceased donor donation involve different processes by the IOTA participant, so we are choosing each of those numbers separately to recognize the potential capacity for each IOTA participant for both living and deceased donor transplantation.

We propose 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 proposed rule, or zero should the national growth rate be negative, resulting in the transplant target for a given PY. We propose 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 in section III.C.3. of this proposed rule. We propose 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 are also proposing that the low volume threshold to be 11 kidney transplants performed for the purposes of calculating the national growth rate. We also propose 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.

We propose 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 propose 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 propose that if the model begins on an any date after January 1, 2025, the trend would also be adjusted.

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 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.

We propose 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, 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 propose that the baseline years, as defined in section III.B.2.c. of this proposed 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 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. 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. We believe 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. 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 are instead proposing 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. 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. However, procurement rates vary nationally depending on variables unique to each geography and local OPO policies.[191] 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. 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. 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 believe this methodology would not be fair to IOTA participants that are smaller in size or achieving lower rates of kidney transplantation.

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

(2) Calculation of Points

We propose 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.

We propose 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 recognize that an IOTA participant might exceed 150 percent of its transplant target, but this is not expected given the investment needed for substantiable transplant infrastructure to consistently support that number of transplants over time.

[191] 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.*

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 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. 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 this proposed rule, suggest that savings would be driven by the effects of increased transplants. We believe 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. 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 believe 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). 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. 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. 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 solicit comment on our proposed achievement domain scoring methodology and alternative methodologies considered.

(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 propose 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 propose 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). For purposes of the model, we propose 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 LIS.
- Recipients of reimbursements from the Living Organ Donation Reimbursement Program administered by the National Living Donor Assistance Center (NLDAC).

We propose 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. However, only 41 percent of Medicare transplants recipients were dually eligible, which would yield a multiplier of 1.1.[192]

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.[193] [194] The 1.2 multiplier represents the ratio of those living with ESRD and those who received transplants. We theorize 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 believe 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 believe 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 believe 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.[195] The areas used in the ADI are defined by Census Block Group, which presents a number of challenges.[196] 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 believe 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 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 part 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 seek 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.

d. Efficiency Domain

We propose to define the ''efficiency domain'' as the performance assessment category in which CMS assesses the IOTA participant's performance a metric intended to improve the transplant process, as described in section III.C.5.d.(1). of this proposed rule, during a PY. The efficiency domain is focused on improving the overall efficiency of the transplant ecosystem.

We propose including OPTN's organ offer acceptance rate 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 this proposed rule.

(1) Organ Offer Acceptance Rate Ratio

With over 90,000 unique patients on the waitlist 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.[197] 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

[192] 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.*

[193] 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.

[194] 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 https://doi.org/10.1111/ajt.16982.*

[195] *Neighborhood Atlas—Home.* (2018). Wisc.edu. *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[196] *https://www2.census.gov/geo/pdfs/reference/GARM/Ch11GARM.pdf.*

[197] 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.*

study found that the probability of receiving a deceased donor kidney transplant within three years of placement on the waiting list varied 16-fold between different kidney transplant hospitals across the U.S.[198] 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.[199] By incentivizing kidney organ offer acceptance, we aim 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 propose to include the organ offer acceptance rate ratio as one of the two metrics of performance. We believe that including this measure in the efficiency domain would encourage IOTA participants to increase the utilization of available organs. We also believe 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 believe 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 recognize that all kidney transplant hospitals are already assessed on the organ offer acceptance rate ratio metric under the OPTN, however, we believe that the IOTA Model sets a higher bar for performance, as discussed in section III.C.5.d.(1).(a). of this proposed rule, rather than clearing the threshold that the OPTN sets at 0.30.[200]

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.[201] Additionally, kidney transplant hospital performance is commonly measured by post-transplant outcomes. We recognize that including pre-transplant measures could allow for a more thorough evaluation of transplant hospital performance and provide insight for patient decision-making.

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 understand the importance of a transplant surgeon's clinical decision-making and respect 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.[202]

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.[203] While a waitlist mortality metric may help assess patient outcomes and experience while waiting for an organ offer,[204] 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 available donor organs available for transplantation. We also recognize 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 believe 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, such as—

- Time from initial evaluation to transplant;

[198] 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.*

[199] 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.*

[200] *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.*

[201] 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. ., & 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.*

[202] 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.*

[203] 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.*

[204] 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.*

- 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.

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.[205] Studies have shown long-standing barriers and disparities to access to transplantation by patient demographics, such as racial/ethnic, sex, socioeconomic, and insurance factors.[206] Disparities are driven by various factors, but we recognize that delays or lack of referrals for evaluation, evaluation criteria that may unintentionally deem a patient not eligible to be placed on a waitlist, and organ acceptance rate variations across kidney transplant hospitals, may exacerbate disparities. 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. 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.[207] Additionally, some studies found considerable variation in referral rates to transplantation by dialysis facilities, proposing significant regional and facility-level variation in care.[208] However, because dialysis facilities are often the primary referrer and are not IOTA participants, we did not propose this measure. We also have 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, we chose not to propose to include waitlist management metrics when assessing IOTA participant performance in the efficiency domain because we believe that 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.[209] 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 do 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 believe 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 solicit comment on our proposed organ offer acceptance rate ratio metric for purposes of assessing performance in the efficiency domain, and the alternatives considered.

(a) Calculation of Metric

We propose 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.[210] 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.[211]

[205] 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.*

[206] 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.*

[207] 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.*

[208] 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 Kidney Transplantation Among Patients With End-Stage Renal Disease in Georgia. *JAMA, 314*(6), 582. *https://doi.org/10.1001/jama.2015.8897.*

[209] 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.*

[210] OPTN. (2022). *OPTN Enhanced Transplant Program Performance Metrics. https://optn.transplant.hrsa.gov/media/r5lmmgcl/mpsc_performancemetrics_3242022b.pdf.*

[211] *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.*

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.[212] We propose to use SRTR data to calculate the OPTN organ offer acceptance rate ratio, as described in section III.C.5.d.(1).(b). of this proposed rule.

Per the SRTR measure, we propose dividing the number of kidney transplant organs accepted by each IOTA participant (numerator) by the risk-adjusted number of expected organ offer acceptances (denominator).[213] 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.[214] We propose 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. Consider the offer of a biopsied kidney 150 nautical miles (NM) away to a candidate who has been on dialysis for 2 years. 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 4.[215]

TABLE 4: 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% 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 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 to paragraph (b)(1) of § 512.426. 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.

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 propose 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, Table 5 summarizes the types of organ offers that we propose 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 propose 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.[216] For purposes of organ offers excluded from the organ offer acceptance rate ratio measure, we

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

[213] Ibid.

[214] SRTR. (2023). Srtr.org. *https://tools.srtr.org/OAModelApp_2205/;* Ibid.

[215] 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).

[216] OPTN. (2023). *OPTN Policies. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

propose to define ''bypassed response'' as an organ offer not received due to expedited placement [217] 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.[218]

TABLE 5: ORGAN OFFERS INCLUDED AND EXCLUDED FROM MEASURE[219]

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).

We believe 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 model is not requiring increased utilization of higher KDPI kidneys that some centers 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.

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.

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.

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 believe may be unfair to IOTA participants that do not.

We seek 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 seek comments on the alternatives we considered. Additionally, we seek comment on our proposed definitions.

(b) Calculation of Points

As described in section III.C.5.b. of this proposed rule, we propose 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 proposed rule, the efficiency domain is weighted lower than the achievement domain but equal to the quality domain to ensure performance measurement is primarily

[217] 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.

[218] 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/.*

[219] 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.*

focused on increasing number of kidney transplants, while still incentivizing efficiency and quality. Within the efficiency domain, we propose that the OPTN organ offer acceptance rate ratio would account for the entirety of the 20 allocated points in that domain.

We propose 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 propose that the IOTA participant would be awarded points equal to the higher of the two scores, up to a maximum of 20 points. We believe 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.

For achievement scoring, we propose that points earned would be based on the IOTA participants' 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. 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.[220] Large variations were still present between kidney transplant hospitals that utilized the same OPO.[221] The probability of transplant was significantly associated with transplant hospitals' offer acceptance rates.[222]

We propose that achievement scoring points be awarded based on the national quintiles, as outlined in Table 6. 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 proposed 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 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 on this metric, we do not expect every IOTA participant to reach top-level performance.

We propose the following Organ Offer Acceptance Rate Achievement point allocation for IOTA participants, as illustrated in Table 6:

- 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.

TABLE 6: 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

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 propose 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 propose to use the same baseline year definition used for participant eligibility, as described in section III.C.3 of this proposed rule, including the rationale for doing so. We separately propose 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

[220] 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*.

[221] 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*.

[222] Ibid.

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 1 to paragraph (c)(1)(ii)(B)(*1*) of § 512.426.

We propose using equation 1 to paragraph (c)(1)(ii)(B)(*1*) of § 512.426 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 are calculated, we propose 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.

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.

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 believed 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 this 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 believe 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.

We considered a continuous scoring range from zero to 15, where IOTA participants may earn a score of any point value instead of bands. We believe 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 are proposing in the quality domain for post-transplant outcomes, as described in section III.C.5.e.(1).(b). of this proposed rule. However, the organ offer acceptance rate ratio metric, unlike post-transplant outcomes, has 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 are not proposing this approach, however, as our analyses using SRTR data indicate 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, 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 believe this scoring method may potentially prevent IOTA participants from narrowing their criteria to only receive selected offers. However, we believe that it is already risk adjusted for organ status inherently in the measure because only organs that are ultimately transplanted are counted in the denominator.

We seek 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.

e. Quality Domain

We propose 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 this proposed rule. We propose 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.

Our goal for the quality domain within the IOTA Model is to achieve acceptable post-transplant outcomes while incentivizing increased kidney transplant volume. We believe that transplant hospital accountability for patient-centricity and clinical outcomes continues post-transplantation. While transplant outcomes have historically received the most attention, often at the exclusion of other factors, we seek to encourage a better balance in the system to offer the benefits of transplant to more patients. Therefore, we are proposing to include one post-transplant outcome measure, as described in section III.C.5.e.(1). of this proposed 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 proposed rule.

(1) Post-Transplant Outcomes

We propose 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 section III.C.5.e.(1).(a). of this proposed 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.

Over the past few decades, advances in immunosuppressive therapies, surgical techniques, and organ preservation methods have resulted in significant improvements in kidney transplantation outcomes.[223] 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.[224]

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).[225] 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.[226]

To safeguard patient outcomes under the IOTA Model, we are proposing to include this measure as a checkpoint. Because there is significant variation in post-transplant outcomes across kidney transplant hospitals, we believe the IOTA Model should promote improvement in outcomes for the benefit of attributed patients. We also believe that this measure would build upon, and complement, existing OPTN and SRTR measures to the maximum extent possible. Additionally, we believe 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 believe 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,[227] and constructing 5-year and 10-year post-transplant measures. 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. 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 believed it was important to measure post-transplant outcomes in terms of graft survival rather than in terms of graft failure. 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.

We considered constructing a continuous patient survival measure that would evaluate patient survival throughout the entirety of the IOTA Model. 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 believe that this type of measure would not disincentivize waitlisting and could potentially increase equity within this population. Additionally, we believe 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 believe this measure

[223] 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/tp0000000000001539*;. 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/10.1177/20543581211017412*; Shepherd, S., & Formica, R. N. (2021). *Improving Transplant Program Performance Monitoring. 8*(4), 293–300. *https://doi.org/10.1007/s40472-021-00344-z.*

[224] 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.*

[225] 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.*

[226] Scientific Registry of Transplant Recipients. Request for Information. Requested on 05/02/2023. *https://www.srtr.org./.*

[227] *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.*

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 believed 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. Glomerular filtration rate (GFR) is a way to assess renal function, and eGFR is the test used to assess renal function in primary clinical care.[228] 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.[229] We recognize 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 feel it was appropriate to propose.[230]

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. 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. 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 this proposed 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 believed 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 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. 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 seek 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 are 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 would further be interested to hear from the public on which factors involved in graft survival are modifiable by the care team.

(a) Calculation of Metric

We propose that for each model PY, CMS would calculate a composite graft survival rate for each IOTA participant, as defined in section III.C.5.e.(1). of this proposed rule, to measure performance in the quality domain as described in section III.C.5.e. of this proposed rule.

We propose to use our own unadjusted composite graft survival rate equation to evaluate post-transplant outcomes. We propose 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 as specified in Equation 1 to paragraph (b)(1) of § 512.428 to evaluate post-transplant outcomes during the IOTA Model performance period.

For example, 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 PY2 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 composite graft survival rate of 0.8 (48 divided by 60).

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,

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[228] 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*.

[229] 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*.

[230] 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*.

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.[231] OPTN follow-up forms are used to identify graft failure and re-transplant dates.[232] We also propose to use OPTN adult kidney transplant recipient follow-up forms [233] to identify graft failure and re-transplant dates for all transplant furnished to kidney transplant patients 18 years of age or older at the time of the transplant. In the proposed equation, we note that the numerator and denominator would not be limited to the attributed IOTA transplant patients. By this, we mean that it could include IOTA transplant patients who have been de-attributed from an IOTA participant due to transplant failure. We believe 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. While we recognize 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 believe 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 invite public comment on our proposed methodology to calculate post-transplant outcomes in the IOTA Model, and on alternatives considered. Although we are proposing an unadjusted composite graft survival rate to measure post-transplant outcomes, we are interested in comments on whether risk risk-adjustments are necessary, and which ones, such as donor demographic characteristics (race, gender, age, disease condition, geographic location), would be significant and clinically appropriate in the context of our proposed approach.

(b) Calculation of Points

As described in section III.C.5.e. of this proposed rule, performance on the quality domain would be worth up to 20 points. Within the quality domain, we propose that the composite graft survival rate would account for 10 of the 20 allocated points. We propose 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 propose that points would be awarded based on the national quintiles, as outlined in Table 7, 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 7: 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 in section III.C.6.c.(2). of this proposed 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

[231] *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.*

[232] *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/.*

[233] *https://unos.org/wp-content/uploads/Adult-TRF-Kidney.pdf.*

our ability to measure improvement year over year due to potentially small numbers.

We seek 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.

(2) Quality Measure Set

We propose 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.

We propose 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).[234] [235] [236] The quality measures that we are proposing share common features. We are proposing 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.[237] 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 are proposing 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 are proposing in section III.C.5.e.(1). of this proposed rule would provide an essential, albeit limited, assessment of the success of a kidney transplant. Finally, we are proposing measures that we believe would incentivize improvement in aspects of post-transplant care that are important to patients and modifiable by IOTA participants.

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.[238] 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.[239]

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. However, we chose to propose three measures and pre-measure development because we want to use them to incentivize and improve patient care. We seek 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. It is worth noting that if we choose fewer measures, then we propose allocating the points accordingly within the remaining measures.

We considered several alternative measures for the quality domain performance assessment. 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 are not proposing 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). 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.[240] We considered whether the PAM® Measure could encourage IOTA participants and IOTA Collaborators, as defined in section III.C.11.d. of this 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.

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 focus on depression can improve health-related quality of life in patients with ESRD.[241] 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.[242] Although the waitlist offers

[234] *collaboRATE.* (2019). Glyn Elwyn. *http://www.glynelwyn.com/collaborate.html.*

[235] *Colorectal Cancer Screening—NCQA.* (2018). NCQA. *https://www.ncqa.org/hedis/measures/colorectal-cancer-screening/ https://www.ncqa.org/hedis/measures/colorectal-cancer-screening/.*

[236] *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.*

[237] 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.*

[238] 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.*

[239] 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.*

[240] *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.*

[241] 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.*

[242] 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.*

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.[243] These factors are likely contributors to high rates of stress and anxiety observed among waitlisted patients.[244] 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 part 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.[245] Additionally, this measure is already being used in the KCC Model.

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. 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.

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.[246] Depression measures are included in the Universal Foundation because successfully treating depression can improve physical health outcomes, in addition to behavioral health outcomes.[247] 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 waitlist, but did not affect likelihood of receiving a kidney transplant.[248] We are not proposing 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 seek 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 seek comment on alternative quality measures considered.

(a) Quality Measure Set Selection, Reporting and Changes

As proposed in section III.C.5.e.(2). of this proposed rule, we are proposing that CMS select and use quality measures to assess IOTA participant performance in the quality domain. We propose 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 propose 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 propose 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 propose 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.

We propose 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 propose 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.

We propose 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 and improvement in performance can no longer be made (''topped out'' measure), as defined in 42 CFR 412.140(g)(3)(i)(A).

[243] 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*.

[244] Ibid.

[245] *CMS ESRD Measures Manual for the 2023 Performance Period*. (2022). *https://www.cms.gov/files/document/esrd-measures-manual-v81.pdf*.

[246] 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 https://doi.org/10.2215/cjn.01210122*.

[247] 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*.

[248] 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*.

- 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.

We propose that CMS would assess the benefits of removing or replacing a quality measure from the IOTA Model on a case-by-case basis. We propose 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 propose 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 propose 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 seek comment on the requirement that IOTA participants report quality measure data to CMS. We additionally seek comment on our proposed process for adding, removing, or replacing quality measures in the IOTA Model.

(b) CollaboRATE Shared Decision-Making Score

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 propose 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 this proposed rule, that would be established by CMS.

We 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. 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.[249] 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.[250] Furthermore, research findings support that shared decision-making with the patient could reduce kidney non-utilization, improve equity,

[249] 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), 26–32. *http://mutex.gmu.edu/login?url=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.*

[250] Stephenson, M.D., & Bradshaw, W. (2018). Shared decision making in chronic kidney disease. Renal Society of Australasia Journal, 14(1), 26–32. *http://mutex.gmu.edu/login?url=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.*

and increase the number of kidney transplants.[251]

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 this proposed rule, and the proposed quality domain post-transplant outcomes metrics, as described in section III.C.5.e.(1). of this proposed rule, we aim 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 believe 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.[252]

We acknowledge that the instrument used for the CollaboRATE Shared Decision-Making Score is generic; however, we have not been able 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 believe 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 seek comment on our proposal to include the CollaboRATE Shared Decision-Making Score as a quality measure for purposes of quality domain performance assessment.

(c) Colorectal Cancer Screening

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.[253] 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.[254] [255] [256]

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.[257] 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.[258]

We are proposing the COL measure for inclusion in our assessment of quality domain performance in the model because we believe 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 propose 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 seek comment on our proposal to include the COL measure as a quality measure for purposes of quality domain performance assessment.

(d) 3-Item Care Transition Measure (CTM–3)

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 propose 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 in section III.C.5.e.(2).(a). of this proposed rule, that would be established by CMS.

[251] 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 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.*

[252] 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.*

[253] 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.*

[254] 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.*

[255] 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.*

[256] 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.*

[257] 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.*

[258] Cancer Moonshot. (n.d.). The White House. *https://www.whitehouse.gov/cancermoonshot/.*

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.[259] Poor understanding of and adherence to immunosuppressive drugs were identified as key elements associated with an increased risk for early hospital readmission.[260] 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.[261] 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 1- and 3-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 seek 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.

(e) Calculation of Points

We propose 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 propose that IOTA participants may 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 was 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 believe it is important to allot more points to them, to recognize the additional operational activities necessary for IOTA participants.

We propose 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 8 illustrates our proposed pay-for-reporting and pay-for-performance timeline. We note that we anticipate establishing a quality performance benchmarks and minimum attainment levels for quality measures in future rule making.

TABLE 8: 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

We propose 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. 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 believe that some IOTA participants may be familiar with this as it is similar to the format within the KCC Model. We recognize 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.

We propose 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). For the CTM–3 and CollaboRATE measures, we propose that

[259] 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.*

[260] 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.*

[261] 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.*

points be awarded based on response rate thresholds, as illustrated in Table 9, 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.

We propose 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 9.

TABLE 9 — 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

We recognize 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 believe a higher threshold may be difficult for IOTA participants to achieve. We also believe 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.

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 believe 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 believe 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 believed 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 proposed 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 seek 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 seek comment on the proposed response rate thresholds and point allocations for measures included in the proposed quality measure set within the quality domain.

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, model 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.[262]

For the IOTA Model, we propose 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 this proposed rule.

The IOTA Model would 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 program expenditures. As described in section III.C.5. of this proposed rule, IOTA participants would be assessed against proposed metrics to assess performance for each PY relative to specified targets, threshold, or benchmarks proposed and determined by CMS. The final performance score, not to exceed a maximum of 100 points, would determine if and how upside and downside risk payments are applied, as described in section III.C.6.c. of this proposed rule. We believe this upside and downside risk approach would be a strong incentive to promote performance improvement.

We seek comment on our proposed two-sided risk payment design to incentivize model performance goals.

b. Alternative Payment Design Overview

There are two payment components in the current Medicare FFS program for organ transplantation. Under the

[262] *https://www.cms.gov/priorities/innovation/key-concepts/risk-arrangements-health-care.*

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 is proposing 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 10. This APM design aligns with the Health Care Payment Learning & Action Network (LAN) Category 3 APM framework in which model 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.[263]

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 a n 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 is not proposing to adjust existing Medicare IPPS payments for kidney transplants furnished to Medicare beneficiaries. Instead, CMS is proposing to make performance-based payments to IOTA participants separate from claims-based payments.

TABLE 10: 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 propose to base performance-based payments on increasing the number of transplants and other metrics of efficiency and quality because: (1) we believe it would be a strong proxy for total cost; (2) it directly aligns with the model's focused goal of increasing access and 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 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 proposed rule, it would also result in savings to Medicare.

While we propose 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 proposed rule, we propose model performance-based payments that would only be based on kidney transplants furnished to attributed patients with Medicare FFS as the primary or secondary insurance.

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 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 is needed for the implications of such a potential waiver, we are not proposing to apply model performance-based payments performed on attributed patients enrolled in MA.

We believe 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 are not proposing 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. Waiving this requirement would be unprecedented and the effects are unknown. We do recognize that the proposed incentives in the IOTA Model would have a larger effect if 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, the IOTA Model would encourage multi-payer alignment with the goal of aligning on goals, incentives, and quality. CMS intends to engage with the payer community, including MA,

[263] *https://hcp-lan.org/workproducts/apm-refresh-whitepaper-final.pdf.*

Medicaid, and commercial payers, to discuss opportunities and approaches for alignment.

We request 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 are 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 desired goals. We also recognized this in the model design by proposing a phased-in approach to two-sided risk, with upside-only applied to the first model PY. We also considered other APM frameworks that would link performance to quality, such as pay-for-reporting and pay-for-performance. We did not propose these frameworks, as they did not align with our goals of establishing two-sided risk accountability for IOTA participants. Recognizing the benefits of a rewards-focused approach, particularly as it relates to quality performance, we did incorporate a rewards-focused performance scoring structure designed as pay-for-reporting and pay-for-performance within the quality domain performance assessment.

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 a main focus of the IOTA Model; that is, 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 are not proposing 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 all 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 limit IOTA participant responsiveness to the model 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 this 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 seek 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 kidney transplants. We also seek feedback on alternative approaches considered, including consideration of MA inclusion. We welcome input on how CMS may be able to work with multiple payers to ensure alignment with the IOTA Model.

c. Performance-Based Payment Method

We are proposing that the final performance score as described in section III.C.5. of this proposed 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 proposed 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 proposed rule. Ultimately, we are proposing 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 proposed 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 propose to establish three final performance score range categories, as illustrated in Table 11, that dictate which type of performance-based payment would apply to an IOTA participant for a given PY.

We propose 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 proposed rule. As proposed and indicated in Table 11, 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 propose 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 proposed rule. In the first year of the model, we propose 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 are also proposing 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 propose 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 proposed rule. We propose that there will be no downside risk payment in the PY 1. We are proposing 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 are proposing to introduce downside risk payments. We propose 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 proposed 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 are opting to propose a neutral zone that would allow for more opportunities and incentives to achieve improvements over time without a large probability of downside risk.

TABLE 11. 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 seek feedback on the use of the final performance scores to determine the upside risk payment, the downside risk payment, and the neutral zone.

(2) Apply Payment Calculation Formula to Final Performance Score

We propose 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 proposed 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 proposed rule.

(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 propose 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 propose a methodology to calculate their upside risk payment using the formula in equation 2, 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 proposed rule.
- Medicare kidney transplants is the number of Medicare kidney transplants furnished by the IOTA participant in a PY.

Equation 2: 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 believe 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 equal upside and downside multipliers across IOTA participants.

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 seek comment on our proposed methodology to calculate the upside risk payment and alternatives considered.

(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 3:

Equation 3: Proposed Downside Risk Payment Calculation Formula

$$\textit{Downside Risk Payment} = \$2{,}000 * ((40 - \textit{Final Performance Score})/40) * \textit{Medicare Kidney Transplants}$$

- $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 are proposing 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 proposed 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 proposed 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 seek comment on our proposed downside risk payment calculation formula, and alternatives considered.

(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 propose that the final performance score, as described in section III.C.6.c.(1). of this proposed 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 seek comment on our proposed neutral zone.

(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 proposed rule and calculate performance-based payments in accordance with the methodology specified in section III.C.6.c. of this proposed rule. We propose to define this process as ''preliminary performance assessment and payment calculations.''

We propose 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 propose 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 propose 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 proposed 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 propose 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 propose 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 propose 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 propose 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 propose 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 seek comment on our proposed payment operations and timeline and alternative considered.

(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 proposed rule, we propose 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 propose 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 propose 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 propose 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 propose 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 believe would allow ample time for IOTA participants to separately review CMS calculations.

We propose 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 propose that CMS will 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 propose 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 propose that CMS would conduct an initial assessment and final assessment of the targeted review. We believe 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.

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 propose that targeted review decisions made by CMS would be final, unless submitted by the IOTA participant or CMS for a CMS Administrator review. We are also proposing to include the reconsideration determination process as outlined in proposed § 512.190 in the IOTA Model.

We note 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 seek comment on our proposals regarding the process by which an IOTA participant could request a targeted review of CMS calculations.

(5) Extreme and Uncontrollable Circumstances

Events may occur outside the purview and control of the IOTA participant that may affect their performance in the model. In the event of extreme and uncontrollable circumstances, such as a public health emergency, we propose 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 are proposing 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 propose 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 propose 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 request comment on our extreme and uncontrollable circumstances policy and whether the determinations by the Quality Payment Program that an extreme and uncontrollable circumstance has occurred should apply to IOTA participants.

7. Data Sharing

a. General

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 propose to provide IOTA participants with certain beneficiary-identifiable data for their Medicare beneficiaries who are attributed patients, upon request. We anticipate that IOTA participants would use this data to better assess transplant readiness and post-transplant outcomes. We also propose to provide certain aggregate data that has been de-identified in accordance with the HIPAA Privacy Rule, 45 CFR 164.514(b), as discussed below, for the purposes of helping IOTA participants understand their progress towards the model's performance metrics.

Specifically, subject to the limitations discussed in this proposed rule, and in accordance with applicable law, including the HIPAA Privacy Rule, we propose 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 proposed rule. We propose that CMS would share 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 proposed rule.

We propose that the beneficiary-identifiable claims data described in section III.C.7.b of this proposed 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 proposed rule. We also note 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

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 propose that, subject to providing the beneficiary with the opportunity to decline data sharing as described in section III.C.10.a of this proposed 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.

We recognize 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 without consent unless a law (statute or regulation) permits the disclosure. Here, the HIPAA Privacy Rule would allow for the proposed disclosure of individually identifiable health information by CMS.

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. 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, 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 previously discussed, 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)).

''Routine uses'' are an exception to this general principle. 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. 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 believe that the proposed data disclosures are consistent with the purposes for which the data discussed in the proposed rule were collected and may be disclosed in accordance with the routine uses applicable to those records.

We propose 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, 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 propose that we would make available beneficiary-identifiable data as described in section III.C.8.b. of this proposed rule for IOTA participants to request for purposes of conducting health care operations 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. 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 believe that improved care coordination would improve outcomes and keep patients engaged in their care.

We also propose 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 this 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 this proposed rule. Finally, we propose 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 this proposed rule.

(2) Quarterly Attribution Lists

We propose that this 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 propose 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 proposed rule. We propose 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 request 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.

(3) Beneficiary-Identifiable Claims Data

We propose to offer certain beneficiary-identifiable claims data to IOTA participants no later than 1 month after the start of each PY, in a form and manner specified by CMS. We propose 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 propose 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 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.

c. Minimum Necessary Data

We propose IOTA participants must limit their beneficiary-identifiable data requests to the minimum necessary to accomplish a permitted use of the data. We propose the minimum necessary Parts A and B data elements may include, but are not limited to, the following data elements:

- Beneficiary Identification (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 propose 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 request 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.

d. Medicare Beneficiary Opportunity To Decline Data Sharing

As described in section III.C.10.a. of this proposed rule, we propose that Medicare beneficiaries must receive notification about the IOTA model. We also propose 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 propose that Medicare beneficiaries would be notified about the opportunity to decline claims data sharing through the notifications proposed in section III.C.10.a. of this proposed rule. We propose 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 propose 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.

We propose that Medicare beneficiaries may not decline to have the aggregate, de-identified data proposed in section III.C.7.f. of this proposed rule shared with IOTA participants. We also propose that Medicare beneficiaries may not decline to have the: initial attribution lists, quarterly attribution lists, and annual attribution reconciliation list as proposed in section III.C.4.b.(2)., b.(3). and b.(4). of this proposed rule shared with IOTA participants. We note that, in accordance with 42 U.S.C. 290dd–2 and its implementing regulations at 42 CFR part 2, CMS does not share beneficiary identifiable claims data relating to the diagnosis and treatment of substance use disorders under this model.

We note 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 are in no way intended to impede existing or future data sharing under other authorities or models.

We request comment and feedback on our proposed policies to enable Medicare beneficiaries to decline data sharing.

e. Data Sharing Agreement

(1) General

As noted in section III.C.7.a. of this proposed rule, we propose 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 propose 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 propose 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 propose 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 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 propose 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.

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. As noted previously in this section of the proposed rule, 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 solicit 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.

(2) Content of the Data Sharing Agreement

We propose 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 propose 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 participant 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.

CMS believes that 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 seeks 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. These data sharing agreement provisions would not prohibit the IOTA participant from making any disclosures of the data otherwise required by law.

CMS also seeks 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, CMS is 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.

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. 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 seek 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, we are 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. These are only examples and are not the only terms CMS would potentially include in the data sharing agreement.

We solicit public comment on this proposal to impose certain requirements in the IOTA data sharing agreement related to privacy, security, data retention, breach notification, and data destruction.

f. Aggregate Data

We propose 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 propose 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 proposed rule.

We seek comment and feedback on our proposal to share aggregate data with IOTA participants.

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 part 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.[264] 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.[265] Prior to placement on the transplant hospital's waitlist, a prospective transplant candidate must receive a psychosocial evaluation, if possible.[266] 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.[267] 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.[268] 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.[269] [270] 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.[271]

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.[272] 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.[273] Racial disparities also exist in transplant wait listing, even after correcting for SDOH.[274] 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.[275] Finally, a recent article in the Journal of the American Medical Association considers how transplant programs factor patient financial resources into waitlist decisions.[276] The authors' review of several studies suggest that socioeconomically deprived patients were proportionally less likely to be selected for placement on a waitlist for an organ transplant. They suggest, 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 this proposed rule.

To improve transparency for those looking to gain access to a transplant waitlist in the transplant program evaluation processes, we propose 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 propose to finalize this requirement only if it is not redundant with other 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 solicit public comments on this proposal and on how often the selection criteria should be updated by the IOTA participant.

(2) Transparency Into Kidney Transplant Organ Offers

Those active on a kidney transplant waitlist may receive organ offers at any time. However, there is currently no

[264] *https://www.ecfr.gov/current/title-42/section-482.90.*

[265] Ibid.

[266] Ibid.

[267] Ibid.

[268] Ibid.

[269] OPTN. (n.d.). *OPTN Policies—Living Donation, Chapter 14. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

[270] 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.*

[271] *https://www.ecfr.gov/current/title-42/section-482.90.*

[272] 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.*

[273] 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.*

[274] 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.*

[275] 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.*

[276] 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.*

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.

We propose 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 propose 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 propose 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.[277] We propose 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 propose that this review may be done on an individual basis in a patient visit, via phone, email, or mail. We believe 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 propose that Medicare beneficiaries would be able to decline this review with the IOTA participant, as some may not wish to have this information. We anticipate that the Medicare beneficiary may decline this review during their next provider visit or over the phone.

We solicit public comment on whether an alternative frequency of sharing of organ offers with the Medicare beneficiary is more appropriate. We also solicit 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 is to provide a balance of transparency and patient engagement in this process without being overly prescriptive or burdensome. We also recognize that there are beneficiaries on the waitlist who may not be eligible to receive an organ offer for multiple years, so we seek 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.

(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 propose 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 proposed rule. We believe 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.

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 propose that CMS would publish the performance results, which should be adequate.

We seek 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.

b. Health Equity Data Reporting

(1) Demographic Data Reporting

As previously discussed in section III.B. of this proposed rule, and throughout this proposed 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.[278] [279] Stratified data can produce meaningful measures that can be used to expose

[277] *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/.*

[278] 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.*

[279] 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.*

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.[280] 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.[281] [282] [283] [284] 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.[285]

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 solicit public comment on the decision not to propose the collection of this data and potential applications.

(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.[286] [287] 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.[288] 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.[289] It also found that health care payers and/or delivery organizations reported a screening prevalence of 55–77 percent, with ''the highest estimate reported among American Hospital Association member hospitals.'' [290] 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 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 proposed 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 seek 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 are seeking 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.

[280] 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.*

[281] American Society for Quality. (2019). *What is root cause analysis (RCA)?* Asq.org. *https://asq.org/quality-resources/root-cause-analysis.*

[282] 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.*

[283] *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.*

[284] 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.*

[285] 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.*

[286] 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.*

[287] *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.*

[288] 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 (June 28, 2022).

[289] 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.*

[290] Ibid.

- 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?

c. Health Equity Plans

To further align with other Innovation Center models and promote health equity across the transplant process, we propose 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 propose 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 propose that the health equity plan must:

- Identify target health disparities. We propose 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 propose 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 propose 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 propose 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 propose 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 propose to define ''health equity goals'' as targeted outcomes relative to the health equity plan performance measures for the first PY and all subsequent PYs.

We propose that once an IOTA participant submits their health equity plan to CMS, CMS will use reasonable efforts to approve or reject the health equity plan within 60 business days. We propose 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 propose 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.

We propose 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.

We propose 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. 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 propose 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 proposed rule. Such remedial actions could include: corrective action such as recoupment of any upside risk payments; or termination from the model.

We solicit feedback on these proposals. We also solicit 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.

9. Overlap With Other Innovation Center Models, CMS Programs, and Federal Initiatives

a. Other Innovation Center Models and CMS Programs

We propose 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 seek 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 propose 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 believe 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 believe 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 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 3 years post-transplant.

We believe 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 believes 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 believe 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 believes 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 proposed 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 proposed rule, where we seek 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 entitled ''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 believe that the proposed IOTA Model supports the policies set out in that final rule. We note 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 note that the number of discarded organs has risen from 21 percent to 25 percent from 2018 to 2022.[291] 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 believe 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 entitled ''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.'' [292]

In December 2021, CMS published an RFI entitled ''Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities'' (86 FR 68594).[293] 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

[291] 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.*

[292] *https://www.federalregister.gov/d/2019-20736/p-87.*

[293] 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.*

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.[294] 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 believe 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 believe that constructing 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 note 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 believe 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,[295] ''[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.[296]
- 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 is not proposing, 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 invite public comments on our proposals to account for overlaps with other CMS programs and models.

10. Beneficiary Protections

a. Beneficiary Notifications

We propose to require IOTA participants to provide notice to attributed patients that the IOTA participant is participating in the IOTA Model. We believe 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 intend to provide a notification template that IOTA

[294] *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/.*

[295] *https://optn.transplant.hrsa.gov/media/5j5dov5s/what_to_expect_performance_reviews.pdf.*

[296] 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.*

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.

We propose requiring IOTA participants to display a notice containing these rights and protections prominently at each office or facility locations 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 seek comment on the proposed requirements for beneficiary notifications.

b. Availability of Services and Beneficiary Freedom of Choice

If finalized, we propose 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 separately proposed in this proposed rulemaking in section II.B of this proposed rule for expansion to all Innovation Center Models with performance periods that begin on or after January 1, 2025. Consistent with these proposed provisions, IOTA participants would 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.

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 expect 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 proposed rule, CMS expects to finalize the proposal that the 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 anti-kickback statute safe harbor set out at § 1001.952(ii)(1), if the proposed arrangements are finalized.

We recognize that there are numerous arrangements that IOTA participants may wish to enter other than the financial arrangements described in the 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 expect 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. We would expect 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. of this proposed 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 propose 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 proposed 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 anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR part 1001.952(ii)), we propose 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 seek comment on the proposed definition of IOTA collaborators and any additional Medicare-enrolled providers or suppliers that should be included in this definition.

d. Sharing Arrangements

(1) General

Similar to the Comprehensive Care for Joint Replacement Payment Model (CJR) (42 CFR part 510), we propose that certain financial arrangements between an IOTA participant and an IOTA collaborator be termed ''sharing arrangements.'' For purposes of the anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)), we propose 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 define that payment as a ''gainsharing payment,'' which is discussed in section III.C.11.d.(3). of this proposed rule. Where a payment from an IOTA collaborator to an IOTA participant is made pursuant to a sharing arrangement, we define that payment as an ''alignment payment,'' which is discussed in section III.C.11.d.(3). of this proposed rule.

(2) Requirements

We propose 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 propose 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 propose 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 propose that the selection criteria must include the quality of care delivered by the potential IOTA collaborator. We also propose 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 propose 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 this section. Therefore, we propose 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.h of this proposed rule).

Finally, we propose 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 seek 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 propose 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 propose 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 proposed 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 requirement 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 propose 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 seek 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 propose 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 seek 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 propose 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 propose 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 seek 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.

(3) Gainsharing Payments and Alignment Payments

We propose several conditions and limitations for gainsharing payments and alignment payments as program integrity protections for the payments to and from IOTA collaborators. We propose 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 calendar 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 propose 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 propose 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 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 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 propose to establish similar requirements for IOTA collaborator's 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 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 propose 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 propose 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 propose 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 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 the 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 the 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 propose 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 seek 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 are particularly interested in 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 are interested in 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 propose 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 propose that 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. 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 propose 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 propose 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 propose 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 seek comment on our proposed aggregate and individual IOTA collaborator limitations on alignment payments.

We propose 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 propose that all gainsharing payments and alignment payments must be made by check, electronic funds transfer (EFT), or another traceable cash transaction. We seek 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 seek 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.

(4) Documentation Requirements

To ensure the integrity of the sharing arrangements, we propose 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 participants 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 propose 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 propose 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 seek 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.

e. Distribution Arrangements

(1) General

Similar to the CJR Model, we propose that certain financial arrangements between IOTA collaborators and other individuals or entities called ''collaboration agents'' be termed ''distribution arrangements.'' For purposes of the anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)), we propose 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 propose 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 propose to define that payment as a ''distribution payment.'' We propose 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 seek 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.

(2) Requirements

We propose 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 propose 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 propose 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 propose 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 propose more flexible standards for the determination of the amount of distribution payments from PGPs, NPPGPs and TGPs for the same reasons we propose 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 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 Model 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 propose 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). This proposal would allow a PGP the choice either to comply with the general standard that the amount of a distribution payment must be substantially based on contribution to the performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA Model activities or to provide its members a financial benefit through the model without consideration of the PGP member's individual contribution to the performance across the achievement

domain, efficiency domain and quality domain. In the latter case, PGP members that are not collaboration agents (including those who furnished no services to attributed patients) would be able 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 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 seek comment on this proposal and specifically 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 propose 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 patients 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 propose the same limitations on the total amount of distribution payments to physicians, nonphysician practitioners, PGPs, NPPGPs and TGPs as we propose for gainsharing payments. In the case of a collaboration agent that is a physician or nonphysician practitioner, we propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 seek 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 seek 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.

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 seek 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.

h. Attributed Patient Engagement Incentives

We believe it is 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 proposed rule, CMS expects to make a determination that the 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 proposed in this section when the incentives are offered in compliance with this policy, specifically the conditions for use of the anti-kickback statute safe harbor set out at § 1001.952(ii)(2), if the proposed Part B and Part D immunosuppressive drug cost sharing support policy and attributed patient engagement incentives are finalized.

(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.[297] 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.[298] Studies have found that low income status decreases the likelihood of waitlisting.[299] One survey of a transplant programs found that 67.3 percent of programs surveys reported frequent or occasional failure to list patients due to concerns regarding ability to pay for immunosuppressive medications.[300] 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.[301]

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.[302] Between 2016 and 2019, the Per-Patient-Per-Year expenditure in the year following transplant in Medicare Parts B and D was $6,947.[303] 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.

We propose 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 (''Part B and Part D immunosuppressive drug cost sharing support'') incurred by attributed patients. As discussed in section III.C.11.i. of this proposed rule, if this rule is finalized, CMS expects to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect the reduction of cost sharing obligations that are made in compliance with this policy and the conditions for use of the anti-kickback statute safe harbor set out at § 1001.952(ii)(2).

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. 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, we are proposing to define eligible attributed patient as an attributed patient that receives immunosuppressive 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

[297] 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.*

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

[299] 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.*

[300] 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.*

[301] *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.*

[302] 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.*

[303] Ibid.

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 kidney transplant may be eligible for the Medicare Part B Immunosuppressive Drug Benefit (Part B–ID) 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 believe 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 are not proposing 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 are proposing 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 believe cost sharing associated with medically necessary immunosuppressive drugs would represent a significant out-of-pocket cost burden to attributed patients who receive immunosuppressive coverage through Part B, the Part B–ID benefit, or Part D, and because we believe 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).

We are proposing 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 believe these policies are 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.

We are proposing 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, 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 do not believe that the 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 are proposing 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 of this proposed rule and § 1001.952(ii)(2).

We considered alternative safeguards for the Part B and Part D immunosuppressive drug cost sharing support policy. 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. Ultimately, we believe 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 cost sharing support policy. 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. Under section 402(d) of the CAA and the implementing regulations at 42 CFR part 407 subpart D 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 believe 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 believe, 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 seek 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 are also soliciting input from interested parties on additional patient-centered safeguards that we may consider to protect cost sharing subsidies made under the proposed Part B and Part D immunosuppressive drug cost sharing support policy, if finalized.

(2) Attributed Patient Engagement Incentives

We believe 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, we propose 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, we are defining post-transplant period to mean the 90-day period following an attributed patient's receipt of a kidney transplant. We are proposing a 90-day post-transplant period because it may take up to 3 months for many individuals to fully recover from a kidney transplant.[304] We are proposing 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.[305] 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 understand 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 believe 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.[306] [307] We understand 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. 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 are 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

[304] *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.*

[305] 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.*

[306] *Ibid.*

[307] 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.*

the kidney transplant waitlist. We believe 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 are 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.[308] Prevalence of depression is reported to decrease after kidney transplant, but may still exceed 20 percent.[309] 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 believe 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 proposed rule, we expect to make the determination that the 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 this proposed rule and the conditions of the safe harbor for CMS-sponsored model patient incentives.

We are proposing 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 to for an attributed patient to achieve or maintain active status on the waitlist, access the kidney transplant procedure, or support the health of the attributed patient or the kidney transplant in the post-transplant period.

We are proposing the following restrictions on the provision of attributed patient engagement incentives. An IOTA participant must include in the written policy approved by CMS prior to offering an attributed patient engagement incentive, 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.

We are proposing 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,

[308] 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.*

[309] 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.*

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 believe 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.

We are also proposing 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 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 proposed rule.

Taken together, we believe 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 the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)).

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. 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.h.(2). of this proposed rule. We took these considerations into account; however, we believe 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, 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. 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.[310] 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 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 are soliciting 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 are further soliciting 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.

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 proposed 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, CMS proposes to waive sections 1881(b) and 1833(a) and 1833(b) of the Act only to the extent necessary to make payments under the IOTA Model. CMS further expects to make a determination, if this rule is finalized, that the 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, if issued. Specifically, we expect to determine 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. However, we determined that use of the safe harbor would encourage the goals of the model. We believe that a successful model requires integration and coordination among IOTA participants and other health care providers and suppliers. We believe the use of the safe harbor would encourage and improve beneficiary experience of care and coordination of

[310] 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.*

care among providers and suppliers. We also believe these safe harbors offer flexibility for innovation and customization. The safe harbors allow for emerging arrangements that reflect up-to-date understandings in medicine, science, and technology.

We seek comment on this proposal, including that the anti-kickback safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)) be available to IOTA participants and IOTA collaborators.

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 propose 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 proposed 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 are proposing 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 are proposing 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 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 invite public comment on these proposed provisions regarding audits and record retention.

13. Monitoring

a. General

We propose 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, which would be performed in accordance with § 512.462, described below in section b of this proposed rule;
- Monitoring quality outcomes and attributed patient data;
- Tracking beneficiary complaints and appeals;
- Monitor 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
- Monitor 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 proposed 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 propose 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 propose 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.

We seek feedback on how CMS should implement this monitoring proposal and any additional concerns regarding the overall monitoring approach.

b. Site Visits

We propose 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 propose 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 propose 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, we propose 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 propose 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 propose 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.

c. Reopening of Payment Determinations

To protect the financial integrity of the IOTA Model, we propose in § 512.462(d) that if CMS discovers that it has made or received 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 invite public comment on these proposed provisions regarding monitoring of the IOTA Model and alternatives considered.

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 CMS Innovation Center regularly monitors model participants for compliance with model requirements.

For the reasons described in section III.C.11. of this proposed 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.

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.[311] 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.[312]

While we considered continuing the ETCLC under the auspices of the IOTA Model, we are proposing 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.

We also considered continuing ETCLC under the aegis of the IOTA Model. We believe 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 believe 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 needs more time to achieve its national aims that could be provided by continuing the ETCLC under the IOTA Model.

We are soliciting feedback on our proposal to conclude the ETCLC with the ETC Model and implement a new learning system specific to the IOTA Model. We are also seeking 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?

16. Remedial Action and Termination

a. Remedial Action

We propose 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 are proposing 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 proposed rule would apply to the IOTA Model. We propose 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 proposed 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 proposed rule, that presents a program integrity risk;

[311] *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.*

[312] Ibid.

• The IOTA participant or its IOTA collaborator is subject to any sanctions 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 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 applicable data sharing agreement.

We propose 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 proposed rule had 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 cost sharing support for Part B and Part D immunosuppressive drugs, or attributed patient engagement incentives in accordance with III.C.11.h(1).

• 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 are proposing that CMS may terminate the IOTA participant, as further described in section III.C.16.b. of this proposed 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 are proposing to discontinue data sharing and reports as a potential remedial action if there are grounds for doing so.

We seek 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.

b. Termination of IOTA Participant From the IOTA Model by CMS

We propose 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; or

++ 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 request comment and feedback on the proposal for termination of an IOTA participant from participating in the IOTA Model.

c. Termination of Model Participation by IOTA Participant

Given the mandatory nature of this model, we propose 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 IOTA Model. As such, while we are proposing 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 proposed rule, we are not proposing voluntary termination by the IOTA participant.

We considered allowing an IOTA participant to voluntarily terminate their participation in the model; however, we believe this went against the mandatory nature of the model and jeopardized our ability to evaluate model success and savings.

We solicit comment and feedback on our proposal not to allow IOTA participants to terminate their participation in the IOTA Model.

d. Financial Settlement Upon Termination

We propose 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 propose that if CMS terminates an IOTA participant for any reason listed in section III.C.16.b of this proposed 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. We propose 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. 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 solicit comment on this proposal and alternative considered.

e. Termination of the IOTA Model

We are proposing that the general provisions relating to termination of the model by CMS in 42 CFR 512.165 would apply to the IOTA Model. 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 or ending. 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 propose that in the event of termination of the model, financial settlement terms would be the same as those proposed in section III.C.16.d. of this proposed rule.

17. Miscellaneous Provisions on Bankruptcy and Other Notifications

a. Notice of Bankruptcy

We propose 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. We propose 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.

b. Change in Control

We propose that CMS could terminate an IOTA participant from the model if the IOTA participant undergoes a Change in Control. We propose 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 propose 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.

c. Prohibition on Assignment

We propose 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 propose that the IOTA participant provide CMS 90 days advance written notice of any such proposed transfer. We propose 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 propose CMS may condition its consent to such transfer on full or partial reconciliation of upside risk payments and downside risk payments. We propose that any purported transfer in violation of this requirement is voidable at the discretion of CMS.

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

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

respond to any of the RFIs would not preclude participation in any future procurement, if conducted.

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

1. Patient-Reported Outcome Performance Measures (PRO–PM)

Chronic kidney disease is both complex and multifaceted and demands inclusive and 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, 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.[313]

Patient-reported measures are those measures where data comes directly from the patient. Broadly, patient-reported data includes patient-reported outcomes (PROs) and ePROs, which is the electronic capture of this data; patient-reported outcome measures (PROMs), which is the structure of how the PRO data is reported (for example, a survey instrument); and patient-reported outcome-based performance measures (PRO–PMs), which are reliable and valid quality measures of aggregated PRO data reported through a PROM and potentially used for performance assessment. PROMs include aspects pertaining health-related quality of life (HRQOL) and symptoms, both of which are essential measures in renal care. HRQOL can vary over time and course of an illness and these types of measures seek to examine the functioning and well-being in physical, mental, and social dimensions of life. It is also impacted by a variety of factors such as treatment, level of health, condition, culture, age, and psychosocial elements.[314]

Using PROMs or PRO–PMs are two ways to include the patient experience and has been acknowledged as a way for patients to provide critical insight about their symptoms, patient experience and quality of life.[315] 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.[316]

In addition to the proposed measures the IOTA Model proposes would be used, as described in section III.C.5.e.(2) of this proposed rule, we would consider incorporating a measure of HRQOL and access to waitlist.

We seek comments on the inclusion of a HRQOL patient-reported outcome measure in the IOTA Model, as well as on the inclusion of an access to waitlist measure. We are seeking input to the questions later in this section, and comment on any aspect of a kidney transplant recipient patient experience measure that should be included in a new measure or existing and validated measurement tools and instruments appropriate for use in the IOTA Model.

- 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 are seeking input on the questions later in this section on

[313] 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.*

[314] Pagels, A.A., Stendahl, M., & Evans, M. (2019). Patient-reported outcome measures as a new application in the Swedish Renal Registry: Health-related quality of life through Rand-36. *Clinical Kidney Journal, 13*(7), 442–449. *https://doi.org/10.1093/ckj/sfz084;* Broadbent, E., Petrie, K.J., Main, J., & Weinman, J. (2006). The Brief Illness Perception Questionnaire. *Journal of Psychosomatic Research, 60*(6), 631–637. *https://doi.org/10.1016/j.jpsychores.2005.10.020;* Mclaren, S., Jhamb, M., & Unruh, M. (2021). Using patient-reported measures to improve outcomes in kidney disease. *Blood Purification, 50*(4–5), 649–654. *https://doi.org/10.1159/000515640.*

[315] 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.*

[316] Ibid.

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?

The integration and implementation of PROMs can be challenging for transplant hospitals as it requires additional resources (that is, appropriate infrastructure with regard to technological capability or data security), time, and there may be uncertainty about how to interpret and use the data to improve patient care.[317] We are also seeking information on implementation challenges and support.

• 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?

2. Access to Waitlist Measure

The kidney transplant waitlist is a list of individuals with ESRD who need a kidney transplant. To be placed on the wait list for a kidney transplant, individuals must be referred and then undergo a comprehensive evaluation process by a transplant center.

Organ transplantation and donation in the U.S. remains highly inequitable amongst racial and ethnic minorities as compared to White Americans, with many factors influencing disparities.[318] As one study notes regarding kidney transplants, ''racial disparities were observed in access to referral, transplant evaluation, waitlisting and organ receipt'' and ''SES [socioeconomic status] explained almost one-third of the lower rate of transplant among black versus white patients, but even after adjustment for demographic, clinical and SES factors, blacks had a 59 percent lower rate of transplant than whites.'' [319]

In addition, Black/African Americans, Hispanics/Latinos, Asian Americans, and other minorities are at a higher risk of illnesses that may eventually lead to kidney failure, such as diabetes and high blood pressure.[320] ''Black/African Americans are almost 4 times more likely and Hispanics or Latinos are 1.3 times more likely to have kidney failure as compared to White Americans.'' [321] Yet those Black/African American and Hispanic/Latinos patients on dialysis are less likely to be placed on the transplant waitlist and also have a lower likelihood of transplantation.[322] In particular, Black/African Americans make up the largest group of minorities in need of an organ transplant and yet the number of organ transplants performed on Black/African Americans in 2020 was 28.5 percent of the number of Black/African Americans currently waiting for a transplant.[323] The number of transplants performed on White Americans, however, was 40.4 percent of the number currently waiting.[324]

We are seeking public comments 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 would not be responding to specific comments submitted in response to this RFI, we intend to use

[317] Ju, A., Cazzolli, R., Howell, M., Scholes-Robertson, N., Wong, G., & Jaure, A. (n.d.). Novel Endpoints in Solid Organ Transplantation: Targeting Patient-reported Outcome Measures. *Transplantation,* 10.1097/TP.0000000000004537. *https://doi.org/10.1097/TP.0000000000004537;* Aiyegbusi, O.L., Kyte, D., Cockwell, P., Anderson, N., & Calvert, M. (2017). A patient-centred approach to measuring quality in kidney care. *Current Opinion in Nephrology and Hypertension, 26*(6), 442–449. *https://doi.org/10.1097/mnh.0000000000000357;* MacLean, C.H., Antao, V.C., Fontana, M.A., Sandhu, H.S., & McLawhorn, A.S. (2021). PROMs: Opportunities, Challenges, and Unfinished Business. *NEJM Catalyst, 2*(11). *https://doi.org/10.1056/cat.21.0280.*

[318] *Inequity in Organ Donation · The Costly Effects of an Outdated Organ Donation System.* (n.d.). Bloomworks.digital. https://bloomworks.digital/organdonationreform/Inequity/; 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.*

[319] 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*

[320] National Kidney Foundation. (2016, January 7). *Minorities and kidney disease.* National Kidney Foundation. *https://www.kidney.org/atoz/content/minorities-KD.*

[321] Ibid.

[322] Reed, R.D., & Locke, J.E. (2019). Social Determinants of Health. *Transplantation,* 1. *https://doi.org/10.1097/tp.0000000000003003.*

[323] *Organ and Tissue Donation—The Office of Minority Health.* (2019). *Hhs.gov. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=27.*

[324] Ibid.

this input to inform any future quality measure efforts.

3. Interoperability

Improved interoperability of software systems and tools used to manage CKD, ESRD, and kidney transplant patients supports the goals of value-based care to encourage care coordination and data-driven decision making to improve outcomes and lower healthcare expenditures. We understand that transplant hospitals rely on transplant specific platforms that are components of market-leading electronic health records (EHRs) or transplant management software that can integrate into an existing EHR. Dialysis organizations and dialysis facilities generally use hemodialysis-specific EHRs from large software companies.[325] EHRs have proprietary components that have historically limited the transfer of clinical data to other EHRs and clinical systems, though interest in exchange, defined at 45 CFR 171.102 as the ability for electronic health information to be transmitted between and among different technologies, systems, platforms, or networks, is growing.[326] Exchange is facilitated by health information networks or health information exchanges, defined at 45 CFR 171.102 as an individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; and that is for a treatment, payment, or health care operations purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164. For the purposes of this proposed rule, we refer to health information networks or health information exchanges, as defined at 45 CFR 171.102, solely as health information exchanges. Health information exchanges facilitate exchange via different mechanisms, such as within a proprietary EHR or across different geographic areas. For example, a transplant hospital may be connected to several local organizations, sometimes called regional health information organizations (RHIOs), that organize and facilitate exchange within a defined geographic area. Dialysis organizations are investing in exchange to streamline the transmission of clinical data and improve care coordination; for example, to support the management of patients across the transition of care between CKD and ESRD.[327]

Interest has also grown in the use of health information technology (HIT), defined at 45 CFR 170.102 as ''hardware, software, integrated technologies or related licenses, IP, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.'' HIT can be leveraged to track transplant referrals, a patient's progress through transplant evaluation, pre-transplant testing results, and waitlist status.[328] HIT can also be used to communicate the status of a transplant referral and support care coordination by allowing for sharing of a patient's records between a dialysis facility and a transplant hospital.

Despite the growth of data exchange and investment in kidney and transplant care HIT, an infrastructure for interoperability that supports the exchange of clinical data across different HIT tools, different approaches to exchange, and proprietary systems and tools is still emerging. We understand that barriers to interoperability create silos that limit care coordination between transplant hospitals, as well as with dialysis facilities and nephrology practices.

Use of health information exchanges that facilitate data sharing across different platforms, tools and non-affiliated health care providers, referred to hereafter as non-proprietary health information exchanges (HIEs), may have special value to participants in value-based care models. For example, a central convener could facilitate data sharing to support care coordination among model participants that are supported by different EHR vendors.[329] Non-proprietary HIEs are particularly important for clinicians and health care organizations that do not use an EHR with a significant share of the market or who engage in broader co-management of their patient population.[330]

Implementation of non-proprietary exchange has been fragmented due to a patchwork of local, State, and Federal investments.[331] The Health Information Technology for Economic and Clinical Health Act (HITECH Act), part of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), made grants to State-based organizations to provide the framework and governance for non-proprietary exchange, the only restriction being geography.[332] As a result, non-proprietary exchange can be regionally based. Non-proprietary exchange facilitated on a regional basis has geographic limitations, including that providers outside an RHIO's area of operation have little incentive to participate in a RHIO with other providers with which they do not share patients.[333] Overcoming regional barriers to exchange could be an important element of realizing the value of non-proprietary exchange in the IOTA Model and for value-based care efforts, more broadly.

The Trusted Exchange Framework and Common Agreement (TEFCA) is an initiative to facilitate exchange of electronic health information across health information networks. In the 21st Century Cures Act, Congress required the National Coordinator to convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally.[334] ONC released the Trusted Exchange Framework, Common Agreement—Version 1, and Qualified Health Information Network (QHIN) Technical Framework—Version 1, which appeared in the **Federal Register** on January 19, 2022 (87 FR 2800). Version 1.1 of the Common Agreement appeared in the **Federal Register** on November 7, 2023 (88 FR

[325] Sutton, P.R., & Payne, T.H. (2019). Interoperability of electronic health information and care of dialysis patients in the United States. *Clinical Journal of the American Society of Nephrology, 14(*10), 1536–1538. *https://doi.org/10.2215/cjn.05300419.*

[326] *HealthIt.gov.* (2019, April 18). *Health Information Exchange | HealthIT.gov. Healthit.gov. https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/health-information-exchange.*

[327] *Interoperability Reduces Provider Burden and Improves Patient Care.* (n.d.). *Fmcna.com.* Retrieved March 18, 2024, from *https://fmcna.com/insights/amr/2019/advancing-interoperability-to-reduce-provider-burden-and-improve/.*

[328] Wu, C., Shah, N., Sood, P., Chethan Puttarajappa, Bernardo, J.F., Mehta, R., Tevar, A. D., Shapiro, R., Tan, H.P., Wijkstrom, M., Sturdevant, M., & Hariharan, S. (2014). Use of the Electronic Health Record (EHR) to Improve the Pre-Transpalnt Process for Kidney and Pancreas Transplantation. *Transplantation, 98,* 833–834. *https://doi.org/10.1097/00007890-201407151-02846.*

[329] Everson, J., & Cross, D.A. (2019). Mind the gap: the potential of alternative health information exchange. *The American journal of managed care, 25.*(1), 32–38.

[330] *Ibid.*

[331] Holmgren, A.J., & Adler-Milstein, J. (2017). Health Information Exchange in US hospitals: The current landscape and a path to improved information sharing. Journal of Hospital Medicine, 12(3), 193–198. *https://doi.org/10.12788/jhm.2704.*

[332] Ibid.

[333] Ibid.

[334] Section 4003(b) of the 21st Century Cures Act (Pub. L. 114–255)

76773). ONC anticipates releasing Version 2 of the Common Agreement in 2024. Version 2 is anticipated to include updates that will support Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) based transactions.[335]

TEFCA has three goals:

- Establish a governance, policy, and technical floor for nationwide interoperability;
- Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value; and
- Enable individuals to gather their health care information.[336]

TEFCA promotes interoperability by defining technical standards and a governing approach for secure information sharing on a national scale. The Recognized Coordinating Entity (RCE) develops, updates, implements, and maintains the Common Agreement. The RCE is also responsible for soliciting and reviewing applications from organizations seeking QHIN status, administering the QHIN designation, operationalizing the Common Agreement, overseeing Qualified Health Information Network (QHIN)-facilitated network operations, and monitoring compliance by participating QHINs.[337]

QHINs are health information networks that agree to the common terms and conditions of exchange with each other, as specified in the Common Agreement, and to the functional and technical requirements for exchange (as specified in the QHIN Technical Framework (QTF)). Each QHIN voluntarily enters into an agreement with the RCE by signing the Common Agreement. On February 13, 2023, HHS announced the first six applicant organizations approved for onboarding as QHINs under TEFCA.[338] On December 12, 2023, TEFCA became operational as five organizations that completed the TEFCA onboarding process were officially designated as QHINs.[339] On February 12, 2024, HHS announced the designation of two additional organizations as QHINs.[340]

CMS acknowledged the importance of TEFCA in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation final rule (87 FR 48780) by adding Enabling Exchange under TEFCA (87 FR 49329) as a new measure under the Health Information Exchange Objective for the Medicare Promoting Interoperability Program. Participants in the Medicare Promoting Interoperability Program may also earn credit for the Health Information Exchange Objective by reporting on the previously finalized Health Information Exchange (HIE) Bidirectional Exchange measure (86 FR 45470).

In the Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules final rule (87 FR 70067 through 70071), CMS also added a new optional measure, Enabling Exchange Under TEFCA, to the Health Information Exchange objective for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category beginning with the CY 2023 performance period/2025 MIPS payment year. Currently, for the CY 2024 performance period/2026 MIPS payment year, MIPS eligible clinicians may fulfill the Health Information Exchange objective via three avenues by reporting: (1) the two Support Electronic Referral Loops measures; (2) the Health Information Exchange Bidirectional Exchange measure; or (3) the Enabling Exchange under TEFCA measure (88 FR 79357 through 79362).

CMS would like to support IOTA participants' interoperability efforts that could lead to best practices in CKD and ESRD care. However, we recognize that given the existing Federal interoperability initiatives, we do not want to create duplicate efforts or create unnecessary burden on IOTA participants. We are seeking comment on how CMS can promote interoperability in the proposed IOTA model; in particular, we seek comment on the extent to which participants are planning on participating in TEFCA in the next 1–2 years, as well as other means by which interoperability may support care coordination in the IOTA model. Any further proposals related to interoperability included in the IOTA model would be proposed through future notice and comment rulemaking.

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 proposed 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.[341] The underutilization of kidney transplantation is particularly

[335] *Trusted Exchange Framework and Common Agreement (TEFCA) | HealthIT.gov.* (n.d.). *www.healthit.gov. https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca.*

[336] *3 . . . 2 . . . 1 . . . TEFCA is Go for Launch.* (2022, January 18). Health IT Buzz. *https://www.healthit.gov/buzz-blog/interoperability/321tefca-is-go-for-launch.*

[337] *https://rce.sequoiaproject.org/.*

[338] *Building TEFCA.* (2023, February 13). Health IT Buzz. *https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/interoperability-electronic-health-and-medical-records/building-tefca.*

[339] Affairs (ASPA), A. S. for P. (2023, December 12). *HHS Marks Major Milestone for Nationwide Health Data Exchange. www.hhs.gov. https://www.hhs.gov/about/news/2023/12/12/hhs-marks-major-milestone-nationwide-health-data-exchange.html.*

[340] *https://www.hhs.gov/about/news/2024/02/12/hhs-expands-tefca-by-adding-two-additional-qhins.html.*

[341] 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/#:~:text=Figure%201%20shows%20that%20a,function%20for%20about%209%20years;* 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.

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.[342]

The proposed IOTA Model would be a mandatory payment model, beginning on January 1, 2025, and ending December 31, 2030, 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 across a set of outcome metrics and quality measures. 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 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).[343] 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 2015–2019 CAGR of 9.2 percent.

For the proposed 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 proposed 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.[344] 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, post-transplant outcomes, and patient equity.

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.[345]

[342] 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*.

[343] 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/*.

[344] 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*.

[345] CMS. 2022. ''Medicare Program; Implementing Certain Provisions of the Consolidated

Continued

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.[346] 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 as required by 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 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory 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).

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 entitled ''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 OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates from the CMS Office of the Actuary, OMB's Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is not significant per section 3(f)(1). Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking. Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this rule does not meet the criteria set forth in 5 U.S.C. 804(2). We solicit comment on 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.[347] 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.[348] Organ offer acceptance ratios [349] and survival rate data (for both years 1 and 3) [350] 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 12:

Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules. Final Rule.'' **Federal Register** 87 FR 66454: 66454–66511.

[346] 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.*

[347] 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.*

[348] Scientific Registry of Transplant Recipients. Adult Recipient Transplants By Donor Type, Center: U.S. Transplants Performed: January 1, 1988–July 31, 2023; For Organ = Kidney; Include: Transplant Year & Recipient Primary Source of Payment. *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/.* Accessed October 17, 2022.

[349] 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.

[350] 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.

TABLE 12: IOTA PERFORMANCE DOMAINS

Domain	Metrics Description	Points
Achievement	The number of transplants performed relative to a target, adjusted for health equity population. Rolling baseline.	60
Efficiency	**20 pts:** Organ offer acceptance rate**,** which is a ratio of observed versus expected organ offer acceptances.	20
Quality	**10 pts**: Composite Post-transplant outcome measure	20
	10 pts: Quality measure set: **4 pts**: CollaboRATE Shared Decision-Making Score (CBE ID:3327). **2 pts**: Colorectal Cancer Screening (COL) (CBE ID: 0034). **4 pts**: The 3-Item Care Transition Measure (CTM-3) (CBE ID: 0228).	
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 $8,000, as shown in equation 4. 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 5. 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 4: IOTA Upside Risk Payment for Scores of 60 and Above

$$\textit{IOTA Lump Sum Payment} = \$8{,}000 * ((\textit{Final Performance Score} - 60)/40) * \textit{Medicare Kidney Transplants}$$

Equation 5: IOTA Downside Risk Payment for Scores of 40 and Below

$$\textit{IOTA Performance Payment} = \$2{,}000 * ((40 - \textit{Final Performance Score})/40) * \textit{Medicare Kidney Transplants}$$

CMS 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.[351] [352] 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.

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 and 3-year failure ratios 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.

CMS assumed that all quality measures would be successfully reported by all IOTA participants in model PYs 1 and 2 (resulting in uniformly maximum scores in that domain). Table II illustrates below that on average, 60 percent of IOTA participants were assumed to achieve maximum quality scores throughout the remaining 4 years of the model; 30 percent were assumed to gradually improve from scores of 5 to 8 in year 3 to scores of 5 to 9 by year 6; and 10 percent were assumed to improve from scores of 2 to 7 in year 3 to scores of 3 to 8 by year 6. We assumed that most IOTA participants would be able to maximize scores early in the testing period and a minority would require more time to reach a higher scoring level. Actual scoring distributions will depend on how CMS ultimately sets targets and how IOTA participants respond.

[351] 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/.*

[352] 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.*

TABLE II: QUALITY SCORE POINTS BY SHARE OF IOTA PARTICIPANTS AND MODEL YEAR

Share of IOTA Participants	Quality Points by Measurement Year			
	MY1	MY2	MY3	MY4 - MY6
10%	10	10	2-7	3-8
30%	10	10	5-8	5-9
60%	10	10	10	10

Table III 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 and beneficiaries enrolled in Medicare as a secondary payer. In any given year, about 30 percent of IOTA participants are projected to receive upside risk payments (ranging from 20 to 40 percent), with only about half of that number of IOTA participants projected to have a downside risk payment in any of years 2 through 6 (ranging from 10 to 23 percent). However, the magnitude of the average downside risk payment is relatively small, and the cumulative projected upside risk payments to IOTA participants, amounting to $36 million, are over 30 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 85 percent of simulation trials. Mean net savings 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.

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

(Projected savings allocated to year of transplant; dollars in millions)

							6-Year Totals		
	2025	2026	2027	2028	2029	2030	Mean	10th Percentile	90th Percentile
Upside Risk Payments	$5	$6	$6	$6	$7	$7	$36	$27	$45
Downside Risk Payments	$0	$0	$0	$0	$0	$0	−$1	−$2	−$1
Total Net Payments	**$5**	**$6**	**$5**	**$6**	**$6**	**$7**	**$35**	$26	$44
Added Transplants	114	244	388	542	652	685	2,625	896	4,669
Impact on FFS Spending	**−$4**	**−$8**	**−$14**	**−$20**	**−$26**	**−$28**	**−$100**	**−$151**	**−$23**
Mean Net Savings	**$1**	**−$2**	**−$8**	**−$14**	**−$19**	**−$21**	**−$65**	−$151	$11

In Table III, 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 400 individual simulation trials and the results for the percentiles are from the top 10th and 90th percentiles of the 400 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.[353] 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 [354] 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

[353] 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/.*

[354] 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).

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.

While the proposed 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 the proposed patient-reported survey measure. We estimate that the average IOTA participant would perform 50 surveys per year and that it would take a clinician 20 minutes to complete the survey. Using base wage information from BLS for a nurse practitioner, we estimate the cost of completing these surveys to be $59.94 per hour. The base wage is then doubled [$59.94 × 2] to account for fringe benefits and overhead to equal an estimated cost of $119.88 per hour.[355] The cost of completing these surveys would then be $1,998 per hospital per year [50 surveys × (⅓) hour per survey × $119.88 hourly wage]. Therefore, the total cost would come out to $179,820 to complete the surveys based on the assumption that 90 active transplant hospitals will be selected as IOTA participants [$1,998 × 90 hospitals = $179,820]. 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 $1.2 million in calendar year 2022. Therefore, the $1,998 cost per IOTA participant to complete the patient-reported survey measure would represent 0.2 percent of the estimated total annual revenue per IOTA participant from DRGs 653 and 008 when Medicare is the primary payer.

1. Regulatory Review Cost Estimation

We estimate the time it will take for a medical and health services manager to review the rule to be 5.33 hours [80,000 words/250 words per minute/60 minutes = 5.33 hours]. Using the wage information from the Bureau Labor of Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $123.06 per hour, including overhead and fringe benefits.[356] The cost of reviewing the rule would therefore be a $655.91 per hospital [5.33 hours × $123.06 per hour = $655.91] or a total cost of $59,031.90 [$655.91 × 90 hospitals = $59,031.90]. 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 $150,859.30 [$655.91 per hospital × 230 hospitals = $150,859.30].[357] In addition, the $655.91 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 when Medicare is the primary payer.

D. Alternatives Considered

Two alternative model specifications were tested for comparison to the results in Table III. The first alternative model specification estimated the impact of including MA beneficiaries as eligible transplant recipients for purposes of upside and downside risk payments to IOTA participants. Currently, MA beneficiaries represent approximately 50 percent of Medicare ESRD beneficiaries receiving transplants, and this share is expected to grow. Over the 6-year period, the projected costs from total net payments increased slightly from $35 million in the primary model specification to $47 million in this first alternative. As expected, most of the impact of the inclusion of MA beneficiaries was observed in added transplants, which increased from 2,625 to 3,428 and from $100 million to $133 million in savings. When MA beneficiaries were included, the mean net savings increased marginally from the primary model specification to $86 million over 6 years, ranging from a savings of $201 million to a cost of $10 million at the 10th and 90th percentiles.

The second alternative model specification excluded MA beneficiaries (that is, returned to the population of the primary model specification) and tested the use of a continuous grading scale instead of bands in the achievement domain for transplants for which the upside risk payments become much more generous (particularly for IOTA participants that would otherwise have resulted in a neutral outcome). The continuous grading scale works by taking the first year equity-adjusted-transplants-to-target ratio for each IOTA participant and divides that by 2.5 times 100 and has a ceiling of 60 points. The reason why the continuous grading scale is costly is because it provides upside risk payments to a much larger group of IOTA participants because it gives sliding scale partial credit for IOTA participants that get above 1.00 in their ratio whereas the proposed method makes them go all the way to a ratio of 1.25 before they get more than 30 points (for example, they jump up to 45 points). Using the continuous grading scale approach, the cumulative projected upside risk payments grew from $36 million in the primary model specification to $118 million in this second alternative. The projected receipts from downside risk payments levied and the projected savings from new transplants were similar to the estimated impacts under the primary model specification. Overall, the mean

[355] 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.*

[356] Bureau of Labor Statistics (BLS). 2022. ''Occupational Employment and Wage Statistics.'' *https://www.bls.gov/oes/current/oes_nat.htm.*

[357] *https://optn.transplant.hrsa.gov.*

net savings for the second alternative significantly changed in sign and magnitude from the primary specification to $15 million in increased costs over 6 years, ranging from a savings of $77 million to a cost of $90 million at the 10th and 90th percentiles. This alternative model specification was not selected because we chose to create bands of performance rather than a continuous scale to provide participants with clear end points to incentivize performance to hit specific thresholds.

E. 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 proposed model is projected to result in over 2,600 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.[358] 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.[359] 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 graft survival outcomes (measured at 1 year post-transplant). The model could also improve the 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 proposed model.

F. Accounting Statement and Table

The annualized monetized benefits and transfers in Table IV were calculated based on constant payments and constant interest rates. Using the row labeled Total as an example for how the results were calculated, the primary estimate of $10 million in total savings was based on a 7 percent discount rate, with a 6-year study period, and a 7 percent net present value of $45.6 million in savings. Net present value for the primary estimate was based on the IOTA Model's mean net savings estimate for years 2025–2030 reported in the bottom row of Table III. The minimum and maximum annualized monetized total benefits and transfers reported in Table IV 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 IV: 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	$6	$4	$8	RIA Table III
Costs to IOTA Participants for Downside Risk Payments	$0	$0	$0	RIA Table III
Benefits via Savings from Increased Transplants	-$16	-$29	-$4	RIA Table III
Total	**-$10**	**-$23**	**$2**	**RIA Table III**

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 V: ADDITIONAL ESTIMATED COSTS FOR 2025-2030

Category	Costs	Source Citation
Burden to IOTA participants	$90,000	section IV.C. Detailed Economic Analysis
Regulatory review	$151,000	section IV.C. Detailed Economic Analysis

G. Regulatory Flexibility Act (RFA)

Effects on IOTA participants in the proposed model include the potential for additional upside risk payments from CMS to the IOTA participant of up to $8,000 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 proposed 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 from approximately 10 to 23 percent of IOTA participants expected to be charged downside risk payments from year to year. By contrast, we project over 6 years that $36 million in total upside risk payments would be made to between 20 to 40 percent of IOTA participants expected to earn payments in the model from year to year.

The RFA requires agencies 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

[358] Hariharan S., Irani A.K., 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.*

[359] Axelrod D.A., Schnitzler M.A., 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/.*

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 $1,998 per IOTA participant per year to complete the patient-reported survey that is included in the quality measure set and the one time cost of $655.91 per IOTA participant to have their medical and health services manager review this rule.

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. We do not believe that this threshold will be reached by the requirements in this proposed rule. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We believe this proposed rule 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 proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately $183 million. This proposed does not mandate any requirements for State, local, or tribal governments, or for the private sector.

I. Federalism

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

VI. Response to Comments

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

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 30, 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 proposes to amend 42 CFR part 512 as follows:

■ 1. The part heading for part 512 is revised to read as follows:

PART 512—STANDARD PROVISIONS FOR 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 Innovation Center Models

■ 4. Revise § 512.100 to read as follows.

§ 512.100 Basis and scope.

(a) *Basis.* This subpart implements certain standard provisions for Innovation Center models, as that term is defined in this subpart.

(b) *Scope.* (1) The regulations in this subpart apply to each Innovation Center model that—

(i) 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; or

(ii) Begins its first performance period on or after January 1, 2025, unless otherwise specified in the Innovation Center model's governing documentation.

(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 the definition of ''Governing documentation'' in alphabetical order;

■ b. Revising the definitions of ''Innovation Center model'', ''Innovation Center model activities'', ''Model beneficiary'', and ''Model participant''; and

■ c. Adding the definitions of ''Performance period'' and ''Standard provisions for Innovation Center models'' in alphabetical order.

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 means 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 means the provisions codified in subpart A of this part.

* * * * *

■ 6. Section 512.190 is added to read as follows:

§ 512.190 Reconsideration review process.

(a) *Applicability of this section.* This section 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. Add 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 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, subject to the health equity performance adjustment, as described in § 512.424.

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).

(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 ana 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 subpart G as defined in § 486.302 of this chapter.

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 § 512.43.

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 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 means the targeted outcomes relative to the health equity plan performance measures for the first PY and all subsequent PYs.

Health equity performance adjustment means the multiplier applied to each kidney transplant performed for a patient from a low-income population when calculating the transplant target as described under § 512.424(e).

Health equity performance plan 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 plan intervention means the initiative(s) the IOTA participant creates and implements to reduce target health disparities.

Health equity project plan means the timeline for the IOTA participant to implement the IOTA participant's the health equity plan.

HHA means a Medicare-enrolled home health agency.

Hospital means a provider as defined by 1861(u) of the Act.

Improvement benchmark rate means 120 percent of the IOTA participants' performance on 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 performances 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 § 512.412(b)(2).

IOTA waitlist patient means a kidney transplant waitlist ESRD 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 0f this chpater.

(2) The criteria to be classified as a rehabilitation hospital or rehabilitation unit set forth in §§ 412.23(b), 412.25, and 412.29 of this chapter for exclusion from the inpatient hospital prospective payment systems specified in § 412.1(a)(1) of this chapter.

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 is 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 of this chapter, and who is registered to a waitlist for a kidney at one or more kidney transplant hospitals.

Low-income population means an IOTA transplant patient in one or more of the following groups:

(1) Medicaid beneficiaries.

(2) Medicare-Medicaid dually eligible beneficiaries.

(3) Recipients of the Medicare low-income subsidy.

(4) Recipients of reimbursements from the Living Organ Donation Reimbursement Program administered by the National Living Donor Assistance Center (NLDAC).

(5) The uninsured.

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.

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, and kidney transplant hospitals that fall below a low-volume threshold of 11.

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 or 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 subpart G of this part) 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) of this chapter).

(5) A clinical social worker (as defined at § 410.73(a) of this chapter).

(6) A registered dietician or nutrition professional (as defined at § 410.134 of this chapter).

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 § 512.458.

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 calendar 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 and quality measure set 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.

Response rate threshold means 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).

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 sections all applicable sections of 1819 of the Act.

Survey and Reporting windows means the two distinct periods where IOTA participants are required to administer a quality measure-related survey or screening to attributed patients or submit patient responses on a quality measure to CMS as set forth in § 512.428(b)(2)(ii).

Target health disparities means 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 § 512.34.

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 § 121.2 of this chapter.

Transplant physician means a physician who provides non-surgical care and treatment to transplant patients before and after transplant as defined in § 121.2 of this chapter.

Transplant program means a component within a transplant hospital which provides transplantation of a particular type of organ as defined in § 121.2 of this chapter.

Transplant recipient means a person who has received an organ transplant as defined in § 121.2 of this chapter.

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 § 121.2 of this chapter, registered to the waiting list, as defined in § 121.2 of this chapter, maintained by a transplant hospital in accordance with § 482.94(b) of this chapter.

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 approach 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 amount 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 would be required to participate in the IOTA Model.

(d) 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 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 to 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 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) *Initial attribution.* (i) 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) *Quarterly attribution.* (i) 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 as 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) *Annual attribution reconciliation.* (i) 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(1) and 512.414(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(x)(1) and (2).

(D) A list of all attributed patients who are de-attributed because they satisfy a de-attribution criterion under § 512.414(e)(4)(i).

(E) The dates on which each attributed patient satisfied a de-attribution criterion as specified under § 512.414(e)(4)(i).

(F) A list of the de-attribution criterion each attributed patient satisfied under § 512.414(e)(4)(i).

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, subject to a health equity performance adjustment as described in paragraph (e) of this section, for that PY, 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) CMS analyzes the baseline years for the relevant PY and identifies:

(i) The highest annual number of deceased donor kidney transplants furnished by the IOTA participant to patients 18 years of age or older during a baseline year; and

(ii) The highest annual number of living donor kidney transplants furnished by the IOTA participant to patients 18 years of age or older during a baseline year.

(2) 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 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 participants 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, except as described in paragraph (d)(2) of this section, 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, except as described in paragraph (e) of this section.

(e) *Health equity performance adjustment.* (1) If a kidney transplant identified under paragraph (d) of this section was performed on a low-income population patient, CMS applies the health equity performance adjustment to that kidney transplant by multiplying each low-income population patient's kidney transplant by 1.2.

(2) CMS sums the number of kidney transplants identified under paragraph (d)(3) of this section and the number of kidney transplants adjusted by the health equity performance adjustment described in paragraph (e)(1) of this section to determine the total sum of kidney transplants performed by the IOTA participant in a PY.

(3) CMS uses the total sum of kidney transplants identified under paragraph (e)(2) of this section and determines the IOTA participant's achievement domain score in accordance with paragraph (f) of this section.

(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 (e)(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
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

TABLE 1 TO PARAGRAPH (f)(2)—IOTA MODEL ACHIEVEMENT DOMAIN SCORING METHODOLOGY—Continued

Performance relative to transplant target	Lower bound condition	Upper bound condition	Points earned
75% of transplant target	Equals 75%	Less than 100%	15
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).

Equation 1 to Paragraph (b)(1): 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 ranking against a national target, 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 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

(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 12 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 1 to Paragraph (c)(1)(ii)(B)(1): IOTA Model Organ Offer Acceptance Rate Ratio Improvement Scoring Equation

$$12\,x\frac{Rate\ Earned\ in\ Performance\ Year\ -Third\ Baseline\ Year\ Rate}{Improvment\ Benchmark\ Rate-Third\ Baseline\ Year\ Rate}$$

§ 512.428 Quality domain.

(a) *General.* For each PY, CMS assesses each IOTA participant on the metrics described under paragraphs (b)(1) and (2) 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).

Equation 1 to Paragraph (b)(1): 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 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) *Quality measure set.* (i) *General.* For each PY, CMS assesses the IOTA participant's performance on the following quality measures:

(A) CollaboRATE Shared Decision-Making Score (CollaboRATE) (CBE ID:3327).

(B) Colorectal Cancer Screening (COL) (CBE ID: 0034).

(C) 3-Item Care Transition Measure (CTM–3) (CBE ID: 0228).

(ii) *Quality measure set survey and reporting requirements.* (A) *General.* For each PY:

(*1*) IOTA participants must survey, where applicable, attributed patients and submit data for the quality measures specified in paragraph (b)(2)(ii)(B) and (C) of this section to CMS during survey and reporting windows in a form and manner and at times established by CMS.

(*2*) CMS notifies IOTA participants of the survey and reporting windows for each quality measure specified in paragraphs (b)(2)(ii)(B) and (C) of this section by the first day of each PY in a form and manner determined by CMS.

(B) *PRO–PM Survey and data reporting requirements.* The IOTA participant must survey and submit data for all attributed patients once a PY, at minimum, on all of the following quality measures in accordance with paragraph (b)(2)(ii)(A) of this section:

(*1*) CollaboRATE.

(*2*) CTM–3

(C) *Process measure survey and data reporting requirements.* The IOTA Participant must administer the COL measure yearly to all IOTA transplant patients who are Medicare beneficiaries.

(3) *Quality measure set selection under the IOTA Model.* (i) *General.* CMS selects quality measures for inclusion in the IOTA Model quality measure set for the purpose of assessing IOTA participant performance in the quality domain.

(ii) *Updating of measure specifications.* CMS uses rulemaking to make substantiative updates to the specifications of the quality measures used in the IOTA Model.

(iii) *Measure retention.* All quality measures selected under paragraph (b)(2)(i) of this section will remain in the quality measure set unless CMS, through rulemaking, removes or replaces them.

(iv) *Measure addition, removal, suspension, or replacement through the rulemaking process.* CMS will use the 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.

(v) *Factors for consideration of removal of quality measures.* CMS weighs whether to remove a measure from the quality measure set specified in paragraph (b)(2)(i) of this section

based on one or more of the following factors:

(A) A quality measure does not align with current clinical guidelines or practice.

(B) 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).

(C) Performance or improvement on a quality measure does not result in better patient outcomes.

(D) 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.

(E) The availability of a quality measure that is more strongly associated with desired patient outcomes for the particular topic.

(F) Collection or public reporting of a quality measure leads to negative unintended consequences other than patient harm.

(G) It is not feasible to implement the quality measure specifications.

(H) The costs associated with a quality measure outweigh the benefit of its continued use in the IOTA Model.

(vi) *Application of measure removal factors.* CMS assesses the benefits of removing or replacing a quality measure from the IOTA Model on a case-by-case basis.

(vii) *Patient safety exception.* (A) If CMS determines that the continued requirement for IOTA participants to submit data on a quality measure raises specific patient safety concerns, CMS may elect to immediately remove the quality measure from the IOTA Model quality measure set.

(B) CMS, upon removal of a quality measure and in a form and manner determined by CMS, does both of the following:

(*1*) 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.

(*2*) Provide notice of the removal in the **Federal Register**.

(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 10 points.

(2) For the quality measure set, as described under paragraph (e) of this section, the IOTA participant may receive up to 10 points.

(i) The IOTA participant may receive a maximum of 4 points for their performance on the CollaboRATE Shared Decision-Making Score.

(ii) The IOTA participant may receive a maximum of 2 points for their performance on the Colorectal Cancer Screening (COL) measure.

(iii) The IOTA participant may receive a maximum of 4 points on the 3-Item Care Transition Measure (CTM–3).

(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 against a national target, inclusive of all eligible 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 target	Lower bound condition	Upper bound condition	Points earned
80th Percentile	Equals 80th percentile	Greater than 80th percentile	10
60th Percentile	Equals 60th percentile	Less than 80th percentile	8
40th Percentile	Equals 40th percentile	Less than 60th percentile	5
20th Percentile	Equals 20th percentile	Less than 40th percentile	3
20th Percentile	N/A	Less than 20th percentile	0

(e) *Quality measure set scoring.* (1) For the first two PYs, CMS awards a maximum of 10 points to an IOTA participant, based on an IOTA participant's performance on the quality measures and requirements under paragraph (b)(2) of this section, as follows:

(i) *Response rate threshold:* For the first two PYs CMS assesses an IOTA participant's performance on quality measures and awards points based on a response rate threshold for each measure.

(A) CMS defines the response rate threshold at the level of complete and accurate reporting for each quality measure specified under paragraph (b)(2)(i) of this section.

(B) CMS determines the response rate threshold for each measure before the start of each PY.

(C) CMS informs IOTA participants of the response rate threshold for each quality measure by the first day of the PY in a form and manner chosen by CMS.

(ii) *Quality measure set scoring methodology.* CMS uses the scoring methodology described in Table 1 to paragraph (e)(1) of this section to determine the following:

(A) The IOTA participant's score on the CollaboRATE;

(B) The IOTA participant's score on the CTM–3; and

(C) The IOTA participant's score on the COL measure for all IOTA transplant patients who are Medicare beneficiaries.

TABLE 1 TO PARAGRAPH (e)(1)—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

(2) For subsequent PYs—

(i) The quality performance score will be phased in such that an IOTA participant must continue to report all measures, but CMS assesses an IOTA participant's performance based on quality performance benchmarks and response rate thresholds, as specified by CMS in future rulemaking, for each quality measure under § 512.428(b)(2); and

(ii) CMS awards a maximum of 10 points to an IOTA participant based on its performance as set forth in paragraph (e)(2)(i) of this section.

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, downside risk payment, or 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 from 100.

(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 $8,000.

(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, IOTA participants with a final performance score below 60 points qualify for the neutral zone and neither owes a downside risk payment to CMS nor receives an upside risk payment from CMS.

(ii) For PYs 2–6, 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 1–6, 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 2–6, 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.

(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 subpart c of this part, 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 consider a targeted review request any policy or methodology, including 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 correct 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 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 time 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 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 including 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; and

(iii) Sign and submit a data sharing agreement with CMS as set forth in paragraph (b)(8) of this section.

(3) CMS 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 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 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, 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.

(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:

(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 under § 512.414(c)(1)(ii).

(C) The quarterly attribution lists that CMS provides to IOTA participants as defined at § 512.402 and under § 512.414(c)(2)(ii).

(D) The annual attribution reconciliation list that CMS provides to IOTA participants as defined at § 512.402 and 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:

(*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; and

(*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) *Transparency into kidney transplant organ offers.* The IOTA participant must do the following for all IOTA waitlist patients who are Medicare beneficiaries during the model performance period:

(1) Inform IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf.

(i) For months in which an organ offer is made, provide notices to each IOTA waitlist patient who is a Medicare beneficiary on a monthly basis that include the following:

(A) The number of times an organ is declined on the IOTA waitlist patient's behalf.

(B) The reason(s) why the organ was declined.

(2) Record in the IOTA waitlist patient's medical record that the patient—

(i) Received the information specified in paragraph (b)(1) of this section; and

(ii) The method by which information was delivered.

(3) Share the information specified in paragraph (b)(1) of this section with the

IOTA waitlist patient's nephrologist or nephrology professional if deemed appropriate by the IOTA participant.

(c) *Review of selection criteria and organ-offer filters.* IOTA participants must 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.

(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]

§ 512.444 Health equity plans.

(a) For PY 2 through PY 6, each IOTA participant must 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) Once the IOTA participant submits their health equity plan to CMS, CMS uses reasonable efforts to approve or reject the health equity plan within 60 business days.

(c) 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.

(d) If CMS determines that the IOTA participant's health equity plan does not satisfy the 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, 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.

(1) If CMS rejects the IOTA participant's health equity plan, in whole or in part, the IOTA participant may not, and must require its IOTA collaborators to not, conduct health equity activities identified in the health equity plan.

(2) [Reserved]

(e) In PY 3, and each subsequent PY, in a form and manner and by the date(s) specified by CMS, the IOTA participant must submit to CMS an update on its progress in implementing its health equity plan. This update must include all of the following:

(1) Updated outcomes data for the health equity plan performance measure(s).

(2) Updates to the resource gap analysis.

(3) Updates to the health equity project plan.

(f) If the IOTA participant fails to meet the requirements described in paragraph (a) of this section, CMS may subject the IOTA participant to remedial action, as specified in § 512.464, including either of the following:

(1) Corrective action such as recoupment of any upside risk payments.

(2) Termination from the model.

Beneficiary Protections, 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 in a clear manner on its public facing website, and to each attributed patient in a paper format.

(iii) Provide this notification to each attributed patient in a paper format.

(b) *Applicability of general Innovation Center model provisions.* (1) The requirement 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 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 *et seq.* 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.

(5) 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.

(6) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(7) 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.

(8) 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 calendar 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 in 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, CJR 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:

(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; and

(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) An IOTA participant may provide attributed patient engagement incentives of the type described in paragraph (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:

(A) An attributed patient achieving and maintaining active status on a kidney transplant waitlist;

(B) An attributed patient accessing the kidney transplant procedure; or

(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 acquired for the minimum amount necessary for an attributed patient to achieve the goals described in paragraph (b)(4)(ii) of this section.

(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 may 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 $1000 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.* (1) The IOTA participant must 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) Retrieval documentation.

(i) IOTA participants must document all retrieval attempts of items that are attributed patient engagement incentives, including the ultimate date of retrieval.

(ii) [Reserved]

(3) The IOTA participant must retain records pertaining to furnished attributed patient engagement incentives and make these 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 (§ 1001.952(ii)(1) of this chapter) is available to protect remuneration furnished in the IOTA Model in the form of Sharing Arrangement's gainsharing payments, Sharing Arrangement's alignment payments, and the Distribution Arrangement's distribution payments that meet all safe harbor requirements set forth in § 1001.952(ii) this chapter, and §§ 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 (§ 1001.952(ii)(2) of this chapter) 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 § 1001.952(ii) of this chapter, and §§ 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 this paragraph (c)(1)(ii), 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) Monitor 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) Monitor the provision of attributed patient engagement incentives provided in accordance with § 512.458.

(x) Monitor out of sequence allocation of kidneys by—

(A) Assessing the frequency at which IOTA waitlists 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 § 512.462) except if there exists reliable evidence that the determination was procured by fraud or similar fault as defined in § 512.464. 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 transplants 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—

(i) Has failed to comply with any model requirements or any other Medicare program requirement, rule, or regulation;

(ii) Has failed to comply with a monitoring or auditing plan or both;

(iii) Has failed to submit, obtain approval for, implement or fully comply with the terms of a CAP;

(iv) Has failed to demonstrate improved performance following any remedial action;

(v) Has taken any action that threatens the health or safety of a Medicare beneficiary or other patient;

(vi) Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model;

(vii) 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;

(viii) 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 will 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 subject to administrative or judicial review.

(3) If CMS terminates the IOTA Model, the financial settlement terms described in paragraph (c) of this section applies.

§ 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 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 (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.

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