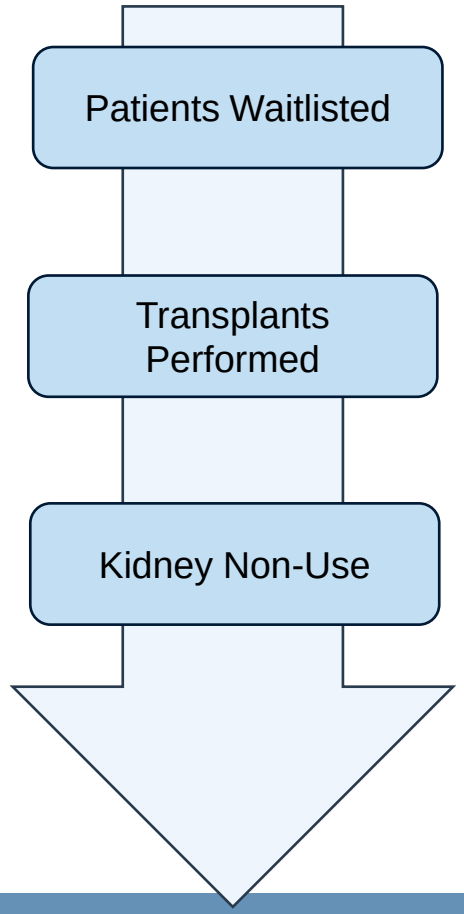
Increasing Organ Transplant Access (IOTA) Model

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Current State of Kidney Transplantation

Kidney Transplantation is the best treatment for most individuals with End-Stage Renal Disease (ESRD). Patients with ESRD who receive a kidney transplant experience improvements in quality of life and reductions in medical spending.



Nearly 90,000 patients are on a waitlist for a kidney transplant in the United States, and approximately 3,000 are added each month.

Approximately 25,000 kidney transplants were performed in 2022.

Despite the gap between organ supply and demand, in 2022, 26.7% of procured kidneys went unused.

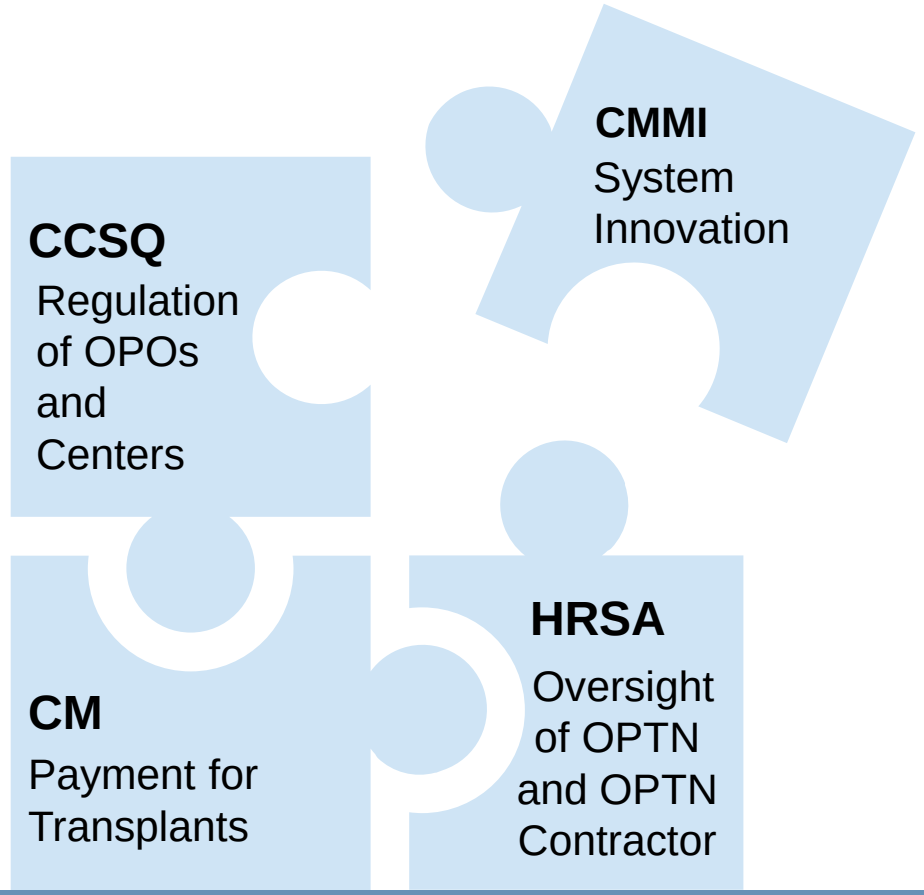
Thirteen Americans die each day waiting for a life-saving kidney transplant.

In 2021, 27.8% of non-Hispanic blacks on the kidney waitlist received a transplant compared to 47.2% of non-Hispanic whites.

Current HHS Efforts in Transplantation

The HHS Organ Transplant Affinity Group (OTAG)

Different components of HHS hold different pieces of the puzzle that make up transplant oversight.



The Organ Transplant Affinity Group (OTAG) has been active since 2021 and was created to coordinate a series of aligned initiatives across CMS and HRSA to increase transplantation through a series of payment, quality and regulatory efforts. The OTAG's goals are to:

1. Ensure access to organ transplantation by reducing variation of pre-transplant/referral practices
2. Improve accountability for U.S. organ transplantation system performance.
3. Increase availability and use of donated organs.
4. Implement policies that promote equitable access to organ transplants
5. Increase patient and family/caregiver education of process

Introducing the Increasing Organ Transplant Access (IOTA) Model

The kidney transplant process involves silos of care, gaps in accountability, disparities, and misaligned financial incentives that value-based care incentives are well-positioned to target.

The IOTA Model would be a mandatory model testing whether payment incentives for selected transplant hospitals can increase the total number of kidney transplants.

Transplant hospitals would focus on:

- Working with other clinicians and providers to overcome barriers to transplant
- Better utilizing the current supply of deceased donor organs
- Assisting more potential donors through the living donor transplant process
- Improving the equity of the transplant process

Participation will be mandatory for 50% of donation service areas (DSAs) within the United States. All eligible transplant hospitals with active kidney programs within a chosen DSA will be required to participate. Eligible transplant hospitals perform 11 or more kidney transplants annually and are non-pediatric facilities.

Target population includes patients on the transplant hospital's waitlist and those who received a transplant from the participant hospital. This will include all patients and not be limited to Medicare beneficiaries.

Measuring Performance

IOTA Model Participants will be assessed based on their performance across the following domains. Each participant will receive a score out of 100 points which will determine the amount paid for each Medicare fee-for-service (FFS) kidney transplant conducted during the performance year. This reserves the highest bonus payments for those performing the highest number of transplants.

Domain	Metrics Included	Points
Achievement	• Number of transplants performed relative to historical benchmark, adjusted for health equity population	60
Efficiency	• Organ offer acceptance rate ratio	20
Quality	• Post-transplant composite graft survival rate • Quality Measure set	20
	Total Performance Score	X/100

Performance Score	Year 1 Adjustment	Year 2-6 Adjustment
60 -100	Upside Payment	Upside Payment
41-59	No Payment	No Payment
0-40	No Payment	Downside Payment

Achievement Domain (60 Points)

This domain will capture a center's performance against the main goal of the model: increasing the overall number of transplants performed relative to a target

Transplant Target = highest number of deceased or living donor kidney transplants performed during baseline years trended forward by the national growth rate

The transplant count includes a **health equity performance adjustment**. Any transplants performed for the underserved population identified in the equity paper (uninsured, Medicaid, Dual Eligible, Medicare LIS, NLDAC-eligible transplants) will count as 1.2 transplants.

Performance Relative to Target	Points Earned
150% of Target and above	60
125% to 150% of Target	45
100% to 125% of Target	30
75% to 100% of Target	15
Below 75% of Target	0

Efficiency Domain (20 Points)

Organ Offer Acceptance Rate Ratio

Organ-offer acceptance will be calculated as a rate ratio of observed organ offer acceptances versus expected organ offer acceptances. Performance will be assessed across all centers nationally.

- In recognition that all participants may not be able to achieve the highest national rank, but still may be performing beyond their previous standards, this metric will be scored in two ways: achievement scoring and improvement scoring
- Participants will be awarded points based on the scoring system – achievement or improvement – that yields the highest number of points.

Efficiency Domain (20 Points) continued

Organ Offer Acceptance Rate Ratio

Achievement Scoring

Performance Relative to Target	Points Earned
80th Percentile ≤	20
60th ≤ and < 80th Percentile	15
40th ≤ and < 60th Percentile	10
20th≤ and < 40th Percentile	6
< 20thPercentile	0

Improvement Scoring

Participants who perform at or above the benchmark rate will automatically receive 12 points. Those that perform at or below their baseline rate will automatically receive zero points.

For all rates in between, the following formula will be used:

$$12\ x\ \frac{Performance\ Year\ Rate\ -Third\ Baseline\ \text{Year}\ Rate}{Benchmark\ Rate\ -Third\ Baseline\ Year\ Rate}$$

Participants will be awarded points based on the scoring system that yields the highest allocation.

*Benchmark rate will be set at 120% of the IOTA participants' performance on the organ offer acceptance rate ratio during the third baseline year for each PY.

Quality Domain

Proposed Composite Graft Survival Rate Measure – 10 points

= Total number of functioning grafts / Total number of completed kidney transplants

This composite metric measures the number of functioning kidney grafts over time at the end of each performance period. For example, at the end of PY1, an IOTA Participant may have completed 100 kidney transplants, and all grafts are surviving at the end of PY1, earning them a score of 100%. By the end of PY2, the participant has completed an additional 100 kidney transplants, but 10 transplants have failed, 9 performed in PY1 and 1 performed in PY2. Their score is now 95%.

Centers will be ranked nationally with points awarded for performance against IOTA Participants and non-IOTA Participants

Performance Relative to National Ranking	Points Earned
80th Percentile ≤	10
60th ≤ and < 80th Percentile	8
40th ≤ and < 60th Percentile	5
20th≤ and < 40th Percentile	3
< 20thPercentile	0

Quality Domain (continued)

Proposed Quality Measure Set – 10 Points

Existing Measures

CollaboRATE Shared Decision-Making Score

- A 3-question patient reported survey measure that assess the degree to the patient was informed of health issues, to listen priorities, and the extent to which the patient's was included in determining next steps.
- Shared decision-making is especially important in deciding what organs are acceptable to the patient for transplant and preparing the patient for the switch from life on dialysis to life with a transplant.

3-Item Care Transition Measure

- A 3-question patient reported measure that assesses whether the \preferences were accounted for in the care plan; whether patients understood their role in self-management; and, whether appropriate medication education was provided
- Medication management is a lifelong endeavor after transplant and critical to long-term graft survival.

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.

Quality Domain (continued)

The NPRM also includes a request for information (RFI) to help guide the development of two potential new measures which could be included in the later years of the model.

New Measure Development

Patient-Reported Experience/Outcome Measure

- One of the greatest of advantages of transplants is the improvement in quality of life experienced over dialysis. There is no industry standard currently to measure how a patient's life improves from dialysis to living with a transplant.

Transplant Waitlist Measure

- 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. While disparities in those who are on the waitlist versus those who receive a transplant are known – disparities in who are referred for a transplant and who subsequently gain access to a waitlist are largely unknown.

Payment Methodology

The participant's performance score will determine the size of the per Medicare FFS kidney transplant performance-based payment they receive. Performance-based payments exist on a continuous scale, with a maximum upside payment of $8,000 for high performers, and a maximum downside payment of $2,000 for low performers.

Payments for Performance Scores greater than or equal to 60 will be calculated using the following formula:

$$Payment\ to\ IOTA\ participant\ per\ Medicare\ FFS\ Kidney\ Transplant = \$8{,}000\ X\ \frac{Score - 60}{40}$$

Beginning year two, payments for Performance Scores less than or equal to 40 will be calculated using the following formula:

$$Amount\ owed\ to\ CMS\ per\ Medicare\ FFS\ Kidney\ Transplant = \$2{,}000\ X\ \frac{40 - Score}{40}$$

Scores between 41 and 59 (inclusive) will receive no adjustment.

Additional Model Policies

Increased Transparency

- Participants will be required to publicly disclose their transplant evaluation criteria and review rejected offers for transplant with their patients.

Health Equity Plans and Health Equity Data Reporting

- Participants will be required to submit health equity plans (HEPs) beginning PY2, and the NPRM includes an RFI on health equity data reporting (HEDR).

Safe Harbors and Flexibilities

- Participants will have access to Anti Kickback Statute safe harbors to enable them to address barriers related to social determinants of health, such as transportation, and attributed patients' out of pocket drug costs.

Next Steps

The Notice of Proposed Rulemaking for the IOTA Model is now live!

- View the Increasing Organ Transplant Access Model Notice of Proposed Rulemaking
  - Comment on the IOTA Model here until July 16, 2024.
- Proposed start date is January 1, 2025
- View a Fact Sheet on the Increasing Organ Transplant Access Model.
- More information on the Increasing Organ Transplant Access Model is available on the Model Webpage

If you are interested in receiving additional information, updates, or have questions about the Increasing Organ Transplant Access Model, please:

- Email the model team at CMMItransplant@cms.hhs.gov.
- Sign up for Email Updates from the model team.

Appendix

Transplant Center Performance Year Two: A

Domain	Metric	Calculation	Performance	Points Earned
Achievement 60 Points	**Number of Transplants**	$= \frac{Number\ of\ Transplants\ Performed}{Target\ Number\ of\ Transplants}$	$\frac{164}{116} = 141\%\ of\ Target$	**60/60**
Efficiency 20 Points	**Organ Offer Acceptance Rate Ratio**	Nationally Ranked or $12x\frac{Performance\ Rate - Baseline\ Rate}{Benchmark\ Rate - Baseline\ Rate}$	1.02 and 50th Percentile with 1.70 Baseline Rate	**10/20** Achievement or 0/20 Improvement
Quality 20 Points	**Composite Graft Survival Rate**	$= \frac{Number\ of\ Grafts\ Surviving}{Number\ of\ Transplants\ Performed}$	116/116 = 100%	**10/10**
	Quality Measures	TBD	Full Credit	**10/10**
Total Score				**90/100**

Transplant Center Performance Year Two: B

Domain	Metric	Calculation	Performance	Points Earned
Achievement 60 Points	**Number of Transplants**	$= \frac{Number\ of\ Transplants\ Performed}{Target\ Number\ of\ Transplants}$	$\frac{208}{280} = 74\%\ of\ Target$	**0/60**
Efficiency 20 Points	**Organ Offer Acceptance**	Nationally Ranked or $12x\frac{Performance\ Rate - Baseline\ Rate}{Benchmark\ Rate - Baseline\ Rate}$	0.53 and 30th Percentile with 0.69 Baseline Rate	**6/20** Achievement or 0/20 Improvement
Quality 20 Points	**Post-Transplant Outcomes**	$= \frac{Number\ of\ Grafts\ Surviving}{Number\ of\ Transplants\ Performed}$	$\frac{208}{208}$ = 100%	**10/10**
	Quality Measures	TBD	Full Credit	**10/10**
Total Score				**26/100**

Transplant Center Payment Year Two: PAUP

Transplant Center A
Score = 90

$$Payment\ per\ Transplant = 8{,}000\ X\ \frac{Score - 60}{40}$$

A will receive a bonus payment of $6,000 for each Medicare FFS kidney transplant performed in year two.

Transplant Center B
Score = 26

$$Negative\ Adjustment\ per\ Transplant = \$2{,}000\ X\ \frac{40 - Score}{40}$$

B will owe CMS $700 for each Medicare FFS kidney transplant performed in year two.