Increasing Organ Transplant Access (IOTA) Model

Welcome Webinar

Center for Medicare and Medicaid Innovation

Finalized February 2025

CMS
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Agenda

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2 | What to Expect for IOTA Participants

3 | What IOTA Participants Can Do to Prepare

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The IOTA Model Final Rule

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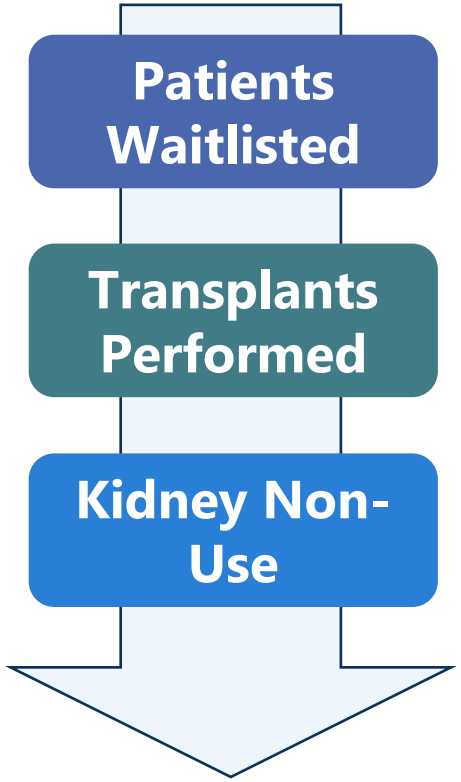
Current State of Kidney Transplantation

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.

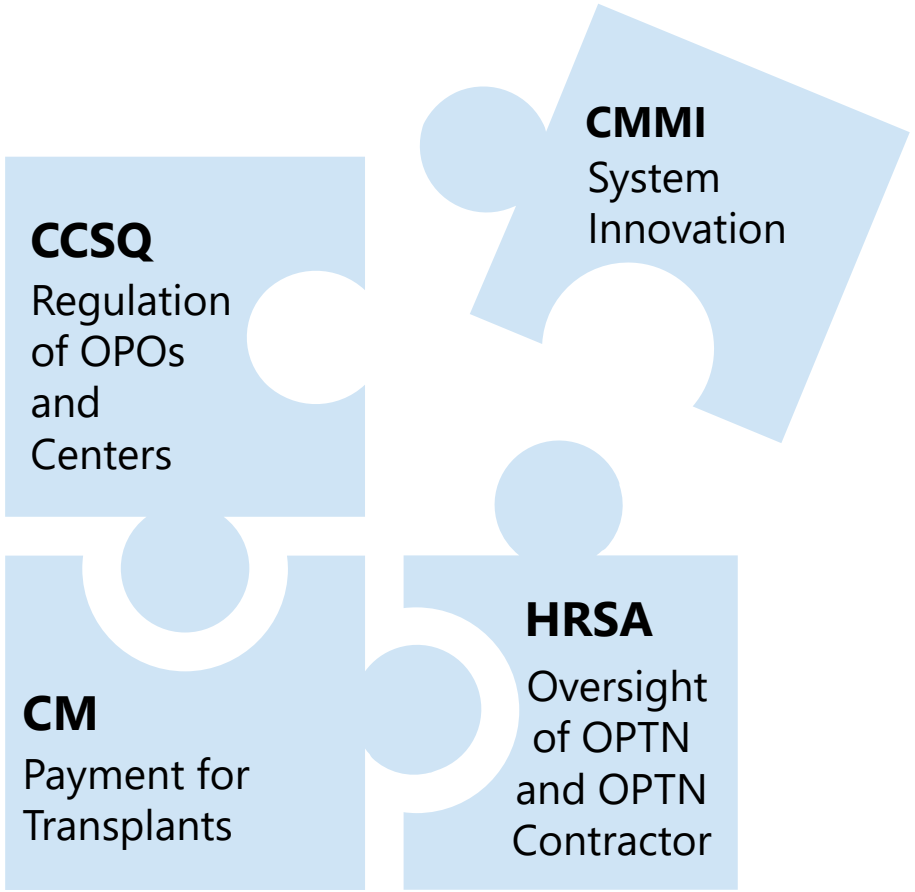
Approximately **27,000 kidney transplants** were performed in 2024.

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.

Current HHS Efforts in Transplantation

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



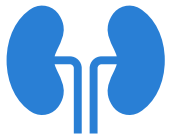
HHS is committed to coordinating a series of aligned initiatives across CMS and HRSA to increase transplantation through a series of payment, quality and regulatory efforts. Goals are to:

- Reduce variation of pre-transplant and referral practices
- Increase the availability and use of donated organs
- Increase accountability for organ procurement and matching
- Empower patients, families, and caregivers to actively engage in the transplant journey

Introducing the IOTA Model

Challenges around the kidney transplant process include siloed care, accountability gaps, disparities, and misaligned financial incentives that value-based care incentives are well-positioned to target.

The IOTA Model is a mandatory model testing whether payment incentives for selected transplant hospitals can increase the total number of kidney transplants, thereby reducing Medicare costs and improving quality of care.



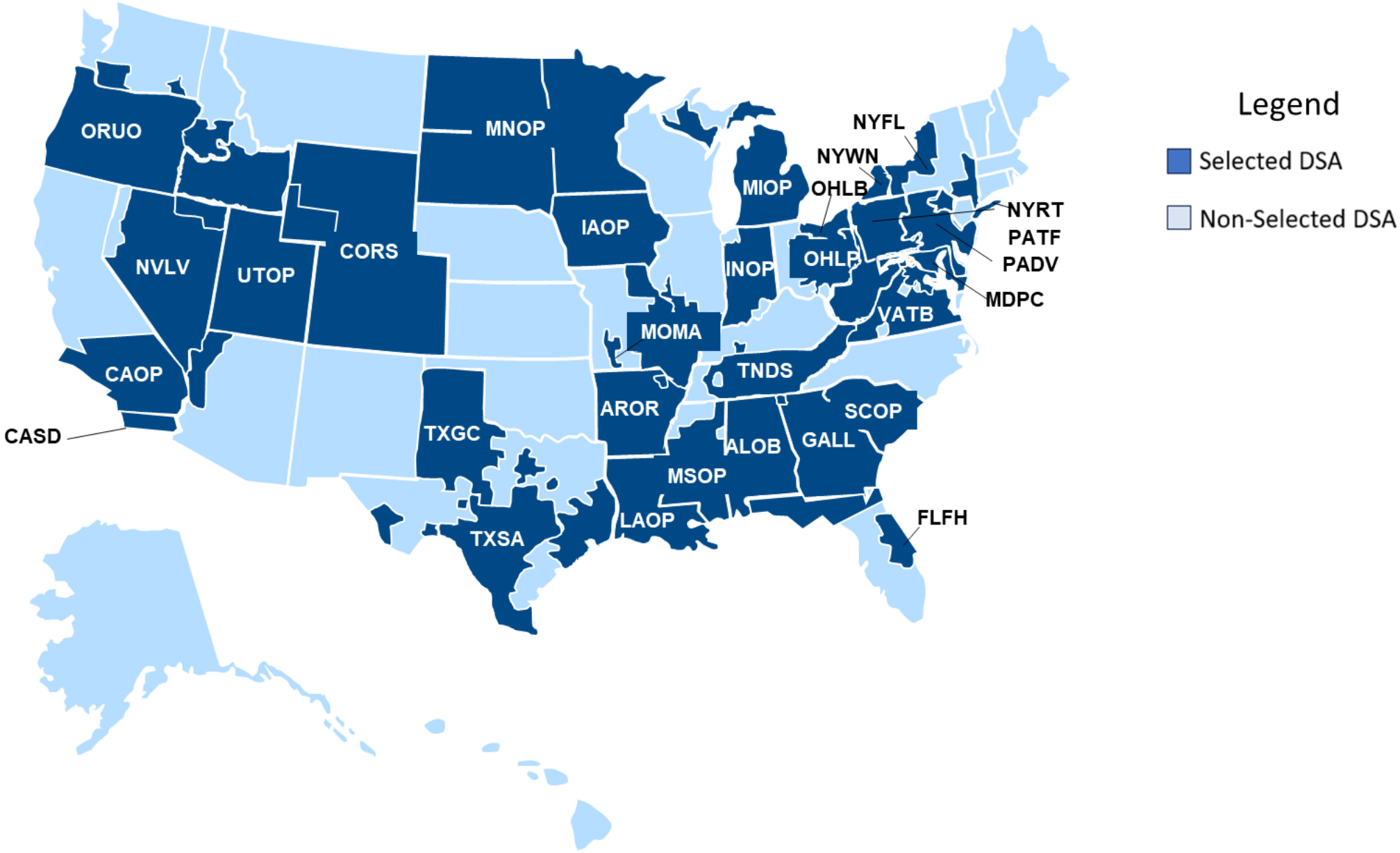
Transplant hospitals would focus on:

- 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

Participation is mandatory for approximately 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, resulting in 103 participants. 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.

DSAs Selected for IOTA Participation



IOTA Participants by DSA

ALOB
- University of Alabama Hospital

AROR
- UAMS Medical Center

CAOP
- Cedars-Sinai Medical Center
- Harbor UCLA Medical Center
- Keck Hospital of USC
- Loma Linda University Medical Center
- Saint Joseph Hospital
- University of California at Los Angeles Medical Center
- University of California Irvine Medical Center

CASD
- Scripps Green Hospital
- Sharp Memorial Hospital
- University of California San Diego Medical Center

CORS
- Advent Health Porter
- Presbyterian/St Luke's Medical Center
- University of Colorado Hospital/Health Science Center

FLFH
- Advent Health Orlando
- Halifax Health

GALL
- Emory University Hospital
- Piedmont Hospital
- Wellstar MCG Health, affiliated with Medical College of Georgia

IAOP
- Iowa Methodist Medical Center
- University of Iowa Hospitals and Clinics Transplant Program

INOP
- Ascension St. Vincent Hospital
- Indiana University Health

LAOP
- Ochsner Foundation Hospital
- Tulane Medical Center
- Willis-Knighton Medical Center

MDPC
- George Washington University Hospital
- Inova Fairfax Hospital
- Johns Hopkins Hospital
- Medstar Georgetown Transplant Institute
- University of Maryland Medical System
- Walter Reed National Military Medical Center at Bethesda

MIOP
- Ascension St. John Hospital
- Henry Ford Hospital
- Mercy Health Saint Mary's
- University of Michigan Medical Center
- William Beaumont Hospital

MNOP
- Avera McKennan Hospital
- Hennepin County Medical Center
- Mayo Clinic Hospital Minnesota
- Sanford Bismarck Medical Center

IOTA Participants by DSA (Continued)

MNOP (continued)
- Sanford Health/USD Medical Center
- Sanford Medical Center Fargo
- University of Minnesota Medical Center, Fairview

MOMA
- Barnes-Jewish Hospital
- SSM Health Saint Louis University Hospital

MSOP
- University of Mississippi Medical Center

NVLV
- University Medical Center of Southern Nevada

NYFL
- State University of New York Upstate Medical University
- Strong Memorial Hospital, University of Rochester Medical Center

NYRT
- James J. Peters VA Medical Center
- Montefiore Medical Center
- Mount Sinai Medical Center
- New York-Presbyterian Hospital/Weill Cornell M
- North Shore University Hospital/Northwell Heal
- NY Presbyterian Hospital/Columbia Univeristy Medical
- NYU Langone Health
- State University of New York, Downstate Medical Center
- University Hospital of State University of New York at Stony Brook
- Westchester Medical Center

NYWN
- Erie County Medical Center

OHLB
- The Cleveland Clinic Foundation
- University Hospitals of Cleveland

OHLP
- Ohio State University Medical Center

ORUO
- Legacy Good Samaritan Hospital and Medical Center
- Oregon Health and Science University
- VA Portland Health Care System

PADV
- Albert Einstein Medical Center
- Christiana Care Health Services
- Geisinger Medical Center
- Hospital of the University of Pennsylvania
- Lehigh Valley Hospital
- Pinnacle Health System at Harrisburg Hospital
- Temple University Hospital
- Thomas Jefferson University Hospital

PATF
- Allegheny General Hospital
- Charleston Area Medical Center
- University of Pittsburgh Medical Center
- VA Pittsburgh Healthcare System

SCOP
- Medical University of South Carolina

IOTA Participants by DSA (Continued)

TNDS
- Erlanger Medical Center
- Saint Thomas Hospital
- University of Tennessee Medical Center at Knox
- Vanderbilt University Medical Center

TXGC
- Baylor Scott and White All Saints Medical Center
- CHI St. Luke's Health Baylor College of Medicine
- Houston Methodist Hospital
- Medical City Fort Worth
- Memorial Hermann Hospital, University of Texas
- Michael E. DeBakey VA Medical Center
- Texas Health Harris Methodist Fort Worth Hospital

TXSA
- Doctor's Hospital at Renaissance
- Methodist Specialty and Transplant Hospital
- North Austin Medical Center
- University Hospital, University of Texas Health Science Center

UTOP
- Intermountain Medical Center
- University of Utah Medical Center

VATB
- Henrico Doctors' Hospital
- Sentara Norfolk General Hospital
- University of Virginia Health Sciences Center
- VCU Health System Authority, VCUMC

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.

Achievement	• Number of transplants performed relative to historical benchmark	60
Efficiency	• Organ offer acceptance rate ratio	20
Quality	• Post-transplant composite graft survival rate	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, thereby reducing Medicare costs and improving quality of care.

Calculation of Transplant Target = the average total number of deceased donor and living donor kidney transplants performed during the relevant baseline years trended forward by the national growth rate.

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.

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

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 non-pediatric kidney transplant hospitals 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

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 15 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:

$$15\ x \frac{Rate\ Earned\ in\ Performance\ Year - \ Third\ Baseline\ Year\ Rate}{Improvement\ Benchmark\ Rate - Third\ Baseline\ Year\ Rate}$$

IOTA 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

Composite Graft Survival Rate Measure – 20 points

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

This composite graft survival rate 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%.

IOTA participants 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 ≤	20
60th ≤ and < 80th Percentile	18
40th ≤ and < 60th Percentile	16
20th ≤ and < 40th Percentile	14
10th ≤ and < 20th Percentile	12
< 10th Percentile	10

Quality Domain (Continued)

The NPRM also included 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 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 those who are referred for a transplant and who subsequently gain access to a waitlist are largely unknown.

Payment Methodology

The IOTA 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 $15,000 for high performers, and a maximum downside payment of $2,000 for low performers.

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

$$Payment\ to\ IOTA\ participant\ per\ each\ Medicare\ FFS\ Kidney\ Transplant = \$15{,}000\ X\ \frac{Score - 60}{40}$$

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

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

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

Additional Model Policies

Increased Transparency

- IOTA participants must publicly post on its website their criteria for evaluating and selecting patients for addition to their kidney transplant waitlist by the end of PY 1.
- IOTA participants must review transplant organ offer acceptance criteria with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist.

Beneficiary Notifications

IOTA participants must provide notice to attributed patients that they are participating in the IOTA Model. IOTA participants must display informational materials in each of their office or facility locations where attributed patients receive treatment, include this notification in a clear manner on its public facing website, and provide this notification to each attributed patient in a paper format.

Safe Harbors and Flexibilities

- The model provides participants certain flexibilities under the Anti-Kickback Statute safe harbor for CMS-sponsored models. Refer to the regulations for more details regarding the protections and requirements.

What to Expect for IOTA Participants

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Beginning of Model Performance Period

The Model Performance Period begins **July 1, 2025.**

But IOTA participants will receive communications from CMS in early 2025. Communications will cover:

4Innovation (4i)

Learning System

Data Sharing

Check-ins with CMS

Onboarding to 4Innovation (4i)

4Innovation (4i)

4Innovation (4i) is a user-friendly system primarily for managing Alternative Payment Model (APM) participation.

4i supports reusable features, allowing APMs to easily manage agreements, participants and contacts, retrieve data files and reports, and access resources and notifications.

The Center for Medicare & Medicaid Innovation (CMMI) conceptualizes a variety of innovative models every year.

As part of the IOTA Model, you will be asked to attest and sign legal agreements between CMS and your organization through the 4i system by creating or updating login credentials in 4i to complete the onboarding process and sign your Data Sharing Agreement to access IOTA reports in 4i Data Hub.

Invitations to join 4i will be sent in the new year. Please make sure CMS has the following information for your participating transplant hospital to receive your invitation:

- Primary Contact Name
- Primary Contact Email Address
- Primary Contact Phone Number

Data Sharing

Once you complete the onboarding process to 4i, you will be able to access data and reports pertinent to your organization. CMS will share the below reports with IOTA Participants.

Data Sharing

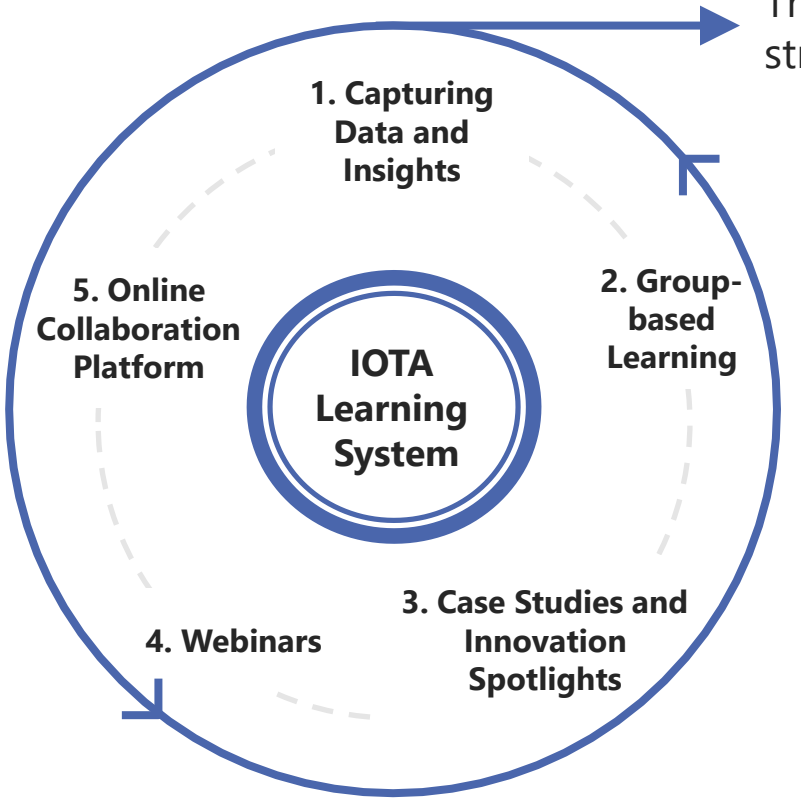
CCLFs/Exclusion Files	Claim and Claim Line Feeds (CCLFs) are generated for assigned or aligned beneficiaries who have not declined to share their data or have not been administratively suppressed. Per CMS policy, substance abuse data is not shared.	Monthly
Patient Attribution Lists	A beneficiary attribution report that contains beneficiary-identifiable data and a list of attributed patients and patients who have been de-attributed from the IOTA participant for the relevant PY.	Quarterly (By 15 days prior to start of PY)
Transplant Target	This report provides the target number of kidney transplants set for each IOTA participant to measure performance in the achievement domain for the relevant PY	Annually (By the first day of PY)
Preliminary Performance Assessment & Payment Calculations	This report provides each IOTA participant with their preliminary performance 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 for the relevant PY.	Annually (Following conclusion of PY)
Final Performance Score	This report provides each IOTA participant with their final performance score and any associated upside risk payment or downside risk payment for the relevant PY.	

IOTA Learning System

During your participation in the model, the Learning System will:

- ✓ Act as ***your partner*** in Implementation and Learning
- ✓ ***Provide key resources*** you need at the start of the model to accelerate implementation
- ✓ ***Ongoing support*** to help you to achieve your goals

Learning System



The **IOTA Learning System** will support participants in achieving the model's strategic goals through:

1. Leveraging CMS and IOTA participant **data to identify best practices and new insights**

2. Sharing with and learning from participants through **Collaboration Communities and Group-based Learning networks**

3. Disseminating a **variety of on-demand resources** including:
   - Case studies and innovation spotlights that highlight promising practices from top performers
   - Webinars including insights from industry leaders
   - IOTA Connect, an online collaboration platform

Check-ins with CMS

Check-ins with CMS

CMS wants to be your partner in the IOTA Model. We would like to meet with you and/or your hospital leadership to answer questions and help build a plan for success.

- What additional data would you like access to?
- What data are you receiving from SRTR or OPTN that CMS should incorporate?
- How can CMS help you succeed in this model?
- What topics are most important to cover in shared learning that you would like to hear from your peers about?

Email the model team at CMMItransplant@cms.hhs.gov to set up a check-in.

Sign up for email updates from the model team.

What IOTA Participants Can Do to Prepare

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Preparing for the IOTA Model

IOTA Participants should begin preparing for the model performance period now. Begin speaking with your leadership about how your organization can get ready.

Review the performance metrics and begin strategic planning:

Domain	Metrics Included	Points	Potential Action Items
Achievement	• Number of transplants performed relative to historical benchmark	60	• Discuss overall hospital strategy with your leadership • Assess organ discard rates • Consider collaborating with OPOs, nephrologists, dialysis facilities
Efficiency	• Organ offer acceptance rate ratio	20	• Review patient organ offer filters • Review waitlist and patient statuses
Quality	• Post-transplant composite graft survival rate	20	• Invest in transplant coordinators to help with post-transplant follow-ups
	Total Performance Score	X/100	

Next Steps

The Final Rule for the IOTA Model is now live!

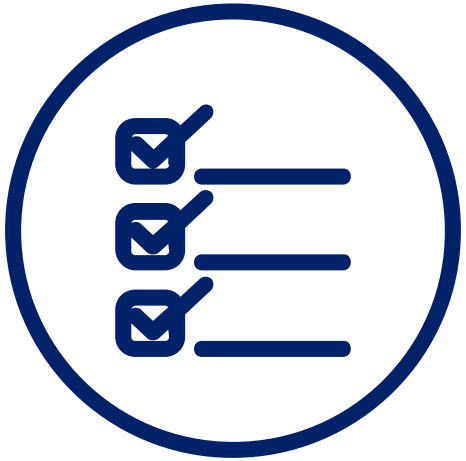
- View the Increasing Organ Transplant Access Model Final Rule.
- View the Increasing Organ Transplant Access Model Notice of Proposed Rulemaking.
- Model start date is July 1, 2025.
- More information on the IOTA Model is available on the model webpage.

If you are interested in receiving additional information, updates, or have questions about the IOTA Model, please:

Email the model team at CMMItransplant@cms.hhs.gov.

Sign up for email updates from the model team.

Please Complete Our Survey



We value your input!

Please click the link posted in the chat to take our brief survey.

Question and Answer (Q&A) Session

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Q&A Session

Open Q&A

Please **submit questions via the Q&A pod** to the right of your screen.

Specific questions about your organization can be submitted to CMMItransplant@cms.hhs.gov.

Closing

Thank You

We appreciate your time and interest!

Please take the survey following this webinar so we can learn how to make our events better.

Do you have questions? Email your comments and feedback to CMMItransplant@cms.hhs.gov with subject line ***IOTA Model Welcome Webinar***

Appendix

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IOTA Participant 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 $15x\frac{Performance\ Rate - Baseline\ Rate}{Benchmark\ Rate - Baseline\ Rate}$	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%	**20/20**
Total Score				**90/100**

IOTA Participant 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 $15x\frac{Performance\ Rate - Baseline\ Rate}{Benchmark\ Rate - Baseline\ Rate}$	0.53 and 30th Percentile with 0.69 Baseline Rate	**6/20** Achievement or 0/20 Improvement
Quality 20 Points	**Post-Transplant Outcomes**	$= \frac{Number\ of\ Grafts\ Surviving}{Number\ of\ Transplants\ Performed}$	$\frac{208}{208} = 100\%$	**20/20**
Total Score				**26/100**

IOTA Participant Payment Year Two: A & B

Transplant Center A
Score = 90

$$Payment\ per\ Transplant = 15{,}000\ X\ \frac{Score - 60}{40}$$

A will receive a bonus payment of $11,250 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.