

Issue Brief

FEDERAL ISSUE BRIEF



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CMS Proposes Mandatory Organ Transplant Model (IOTA)

The Centers for Medicare & Medicaid Services (CMS) are proposing a mandatory payment model “to 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 model would run from January 1, 2025 for six years ending December 31, 2030.

The proposal is scheduled to be published in the **Federal Register** on May 17. As written, a 60-day comment period is being provided commencing upon “Publication.” A copy of the rule is currently available at: <https://public-inspection.federalregister.gov/2024-09989.pdf>.

Comments

As usual no table of contents has been provided. Again, we are including page numbers in red corresponding to items in the rule.

CMS says that “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.” (Page 14)

Yes, it is obvious that many more kidney transplants could be available as noted in the proposal. But to claim such a short fall results in poorer outcomes seems absurd. CMS states also that people “with ESRD who receive transplants have better outcomes than people who receive dialysis.” (Page 50)

Proposed Increasing Organ Transplant Access (IOTA) Model (Page 26)

The IOTA Model payment structure is intended to promote IOTA participant accountability by linking performance-based payments to quality. “We (CMS) 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.”

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. (Page 27)

Provisions of the Proposed Regulation (Page 70)

According to CMS’ press release accompanying this proposal, CMS says “out of the 257 transplant hospitals in the country, an estimated 90 would be required to participate in the proposed six-year model beginning January 1, 2025.”

CMS proposes 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.

CMS proposes to define "transplant hospital" as a hospital that furnishes organ transplants as defined in 42 CFR 121.2.

CMS is 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. CMS proposes 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. (Page 77)

CMS proposes to select eligible kidney transplant hospitals for participation in the IOTA Model using a stratified sampling of approximately half of all Donation Service Areas (DSAs) nationwide. (Page 79)

The proposed approach for IOTA participant selection is as follows: (Page 81)

- Assign all DSAs to a Census Division. CMS is proposing to combine the Middle Atlantic and New England Census Divisions for the purposes of this selection methodology.
- Determine the kidney transplant hospitals located within each DSA.
- Identify the eligible kidney transplant hospitals located within each DSA.
- 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.
- 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.
- 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.
- Randomly select 50 percent of remaining DSAs in each group.

Proposed Attributed Patient Population (Page 86)

CMS proposes 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 regardless of payer type and waitlist status, who is alive, 18 years of age or older, and is registered on a waitlist to one or more IOTA participants, as identified by the Organ Procurement and Transplantation Network (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").

Method and Scoring Overview (Page 100)

CMS proposes to assess performance across three domains: (1) achievement domain; (2) efficiency domain; and (3) quality domain.

CMS proposes 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.
- 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. 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.

CMS proposes 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). (Page 113)

The following table illustrates how an IOTA participant’s performance would be assessed against its transplant target.

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

Health Equity Performance Adjustment (Page 116)

CMS proposes 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.

Efficiency Domain (Page 119)

The efficiency domain is focused on improving the overall efficiency of the transplant ecosystem. CMS proposes to include the organ offer acceptance rate ratio as one of the two metrics of performance.

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

CMS proposes the following Organ Offer Acceptance Rate Achievement point allocation for IOTA participants, as illustrated in the following table. (Page 131)

Organ Offer Acceptance Rate Achievement Scoring

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
80 th Percentile relative to target OR for comparison	Equals 80 th percentile	Greater than 80 th percentile	20
60 th Percentile	Equals 60 th percentile	Less than 80 th percentile	15
40 th Percentile	Equals 40 th percentile	Less than 60 th percentile	10
20 th Percentile	Equals 20 th percentile	Less than 40 th percentile	6
20 th Percentile	N/A	Less than 20 th percentile	0

Quality Domain (Page 135)

CMS proposes 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. The quality domain is focused on monitoring post-transplant care and quality of life for IOTA transplant patients.

CMS proposes that the composite graft survival rate would account for 10 of the 20 allocated points. CMS proposes 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. (Page 143)

Composite Graft Survival Rate Scoring

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

For purposes of quality measure set performance scoring, CMS proposes 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. (Page 158)

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

Payment (Page 161)

CMS proposes to establish three final performance score range categories, as illustrated in the table below, that dictate which type of performance-based payment would apply to an IOTA participant for a given PY. (Page 168)

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

(a) Upside Risk Payment (Page 170)

If an IOTA participant's final performance score would qualify them for the upside risk payment, CMS proposes a methodology to calculate their upside risk payment using the formula in the equation below.

Upside Risk Payment = \$8,000 * ((Final Performance Score - 60) / 40) * Medicare Kidney Transplants
(Page 171)

(b) Downside Risk Payment (Page 172)

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 using the following formula.

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

(c) Neutral Zone (Page 173)

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), CMS proposes that the final performance score would qualify the IOTA participant for the neutral zone, where no upside risk payment or downside risk payment would apply.

Data Sharing (Page 179)

CMS spends some 25 pages regarding data and data sharing.

Overlap with Other Innovation Center Models, CMS Programs, and Federal Initiatives

(Page 204)

CMS proposes 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 the agency seeks comments on proposals to account for overlap.

Beneficiary Protections (Page 214)

CMS proposes to require IOTA participants to provide notice to attributed patients that the IOTA participant is participating in the IOTA Model.

Financial Arrangements and Attributed Patient Engagement Incentives (Page 215)

CMS spends nearly 40 pages addressing financial arrangements and gain sharing.

Final Thoughts

This is an interesting rule to say the least. It reads more like a report than a proposal. There are some 359 footnotes in the document.

CMS has explained in detail what it is mandating and what alternatives it considered.

To a large extent, CMS appears to be implementing this payment model with much unknowns. What is clear is CMS' desire to implement more quality measures but the quality issue itself raises its own concerns.

While this is an upside and downside risk model, CMS places numerous constraints on both sides of the payment adjustments. Therefore, the limited payment incentives may not achieve the proposal's intended results – more quality and savings to Medicare.

Finally, this analysis does not reflect all issues being presented.