# Issue Brief

FEDERAL ISSUE BRIEF

*Analysis provided for MHA by Larry Goldberg, Goldberg Consulting*

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## Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model

The Centers for Medicare and Medicaid Services (CMS) have issued a proposed rule that would update and revise the Increasing Organ Transplant Access (IOTA) Model for Performance Year (PY) 2.

A copy of the 115-page rule is currently available at: https://public-inspection.federalregister.gov/2025-22543.pdf. The rule is scheduled for publication on December 11. A 60-day comment period is provided.

The Increasing Organ Transplant Access (IOTA) Model is a 6-year mandatory alternative payment model being tested by the CMS Innovation Center that began on July 1, 2025, and will end on June 30, 2031. The IOTA Model is testing whether performance-based incentives paid to or owed by participating kidney transplant hospitals can increase access to kidney transplants for kidney transplant waitlist patients, while preserving or enhancing quality of care and reducing Medicare expenditures. CMS has selected 103 kidney transplant hospitals to participate in the IOTA Model and will be measuring and assessing the participating kidney transplant hospitals' performance during each performance year (PY) across three performance domains: achievement, efficiency, and quality.

### Comments

This program was finalized in 2024. Each IOTA participant's final performance score will determine whether: (1) CMS will pay an upside risk payment to the IOTA participant; (2) the IOTA participant will fall into a neutral zone where no performance-based incentive payment will be paid to or owed by the IOTA participant; or (3) the IOTA participant will owe a downside risk payment to CMS. For a final performance score greater than 60, CMS will apply the formula for the upside risk payment, which will be equal to the IOTA participant's final performance score minus 60, then divided by 40, then multiplied by $15,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to attributed patients with Medicare fee-for-service (FFS) as their primary or secondary payer during the PY. Final performance scores below 60 in PY 1 and final performance scores of 40 to 60 (inclusive) in PYs 2 through 6 will fall in the neutral zone where there will be no payment owed to the IOTA participant or CMS.

Here is another CMS payment system that relies on a complex scoring system to determine any payment adjustments.

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. Again, the issue of Medicare outlays appear to be the reason for these rules.

There is no table-of-contents. As usual we are adding page numbers.

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**Proposed Changes to the Increasing Organ Transplant Access (IOTA) Model** (Page 14)

Participation in the IOTA Model is mandatory for approximately 50 percent of all eligible kidney transplant hospitals in the United States, which were selected by a stratified random sampling of donation service areas ("DSAs").

CMS is proposing at § 512.412(a)(1) to raise this low volume threshold from a minimum of 11 kidney transplants performed annually during each of the baseline years to a minimum of 15 kidney transplants performed annually during each of the baseline years. CMS is also proposing this provision in response to its experience in operating the model. IOTA participants who are above the current minimum threshold of 11 kidney transplants performed annually, but below the updated proposed threshold of a minimum of 15 kidney transplants performed annually are still quite small and have indicated structural difficulties in achieving the goals of the model and complying with the requirements of the model. This updated low volume threshold is designed to balance accommodating the needs of smaller kidney transplant hospitals to ensure that their transplant programs can remain viable and continue to serve their communities, while also trying to ensure a sufficient volume of kidney transplant hospitals to be able to test the model.

CMS is proposing at § 512.412(a)(3) to exclude kidney transplant hospitals that are a MTF or VA medical facility from being eligible to participate in the IOTA Model.

To account for proposed kidney transplant hospital participant eligibility criteria modifications at proposed § 512.412(a)(1) and (3), CMS proposes updating the language at § 512.412(a). Specifically, CMS proposes replacing "meets both" with "meets all" to specify that a kidney transplant hospital is eligible to be selected as an IOTA participant, in accordance with the methodology described in proposed § 512.412(b)(3), if the kidney transplant hospital meets all of the eligibility criteria at § 512.412(a).

CMS is proposing at § 512.428(b)(2) to include a risk-adjustment methodology in the composite graft survival rate calculation. Specifically, CMS proposes at § 512.428(b)(2)(i)(A) and (B) that CMS would, in accordance with § 512.428(b)(1) through (3), risk-adjust the composite graft survival rate to account for multiple transplant recipient and donor characteristics, that includes at minimum the following:

- Transplant recipient characteristics:

  ++ Age.

  ++ Sex.

  ++ Kidney function (eGFR/creatinine).

  ++ Diabetes status.

  ++ Hypertension with or without cardiovascular disease.

  ++ Human leukocyte antigen (HLA) mismatch.

  ++ Plasma renin activity (PRA) levels.

- Donor characteristics:

  ++ Age.

  ++ Sex.

  ++ Kidney function (eGFR/creatinine).

  ++ Diabetes status.

  ++ Hypertension history with or without cardiovascular disease.

  ++ Cardiovascular disease.

  ++ Human leukocyte antigen (HLA) mismatch.

  ++ Plasma renin activity (PRA) levels.

  ++ Cause of death.

  ++ Donation after cardiac death.

***Payment*** (Page 43)

For downside risk payments, beginning in PY 2, CMS will calculate the downside risk payment by subtracting the IOTA participant's final performance score from 40, divide that number by 40, multiplying the resulting amount by $2,000 and multiplying that amount by the total number of Medicare kidney transplants performed by the IOTA participant during the relevant PY.

CMS is considering to decrease the maximum upside risk payment from $15,000 to $10,000 per Medicare kidney transplant should CMS update the definition of Medicare kidney transplant to include MA beneficiaries. (Page 45)

***Determine Final Performance Score Range Category*** (Page 46)

CMS proposes at § 512.430(b)(1) to clarify that if in PYs 1-6, the IOTA participant's final performance score is above 60 points, the IOTA participant qualifies for an upside risk payment. Additionally, CMS proposes at § 512.430(b)(2)(ii) to clarify that for PYs 2 through 6, if an IOTA participant's final performance is between 40 to 60 points (inclusive), the IOTA participant qualifies for the neutral zone. Finally, CMS proposes at § 512.430(b)(3) to clarify that if an IOTA participant's final performance score is below 40 points in PYs 1 through 6, the IOTA participant qualifies for a downside risk payment.

**Final Comments**

While this is a proposed rule, CMS is seeking comments on a majority of the items being proposed. After reviewing the proposed rule, the number one goal seems to simply reduce Medicare spending.

CMS appears to have shifted from simple prospective payment systems to convoluted, complex and difficult scoring programs to achieve program savings.

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