Issue Brief
FEDERAL ISSUE BRIEF

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

May 30, 2026

CMS Releasing Final Alternative Payment Model Updates and Increasing Organ Transplant Access (IOTA) Model

The Centers for Medicare and Medicaid Services are issuing a final rule regarding Alternative Payment Model Updates and the Increasing Organ
Transplant Access (IOTA) Model. This final rule will update and revise the IOTA Model for Performance Year (PY) 2, which will begin on July 1, 2026, and for future PYs.

A display copy of the rule is available at: https://public-inspection.federalregister.gov/2026-10890.pdf. The rule is scheduled for publication in the June 1 ***Federal Register.***

CMS issued rules on this topic in 2024 and 2025, and is noting many changes in this rule regarding those previous issued items.

In 2024, CMS finalized that a kidney transplant hospital is eligible to be selected as an IOTA participant if it 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; and (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.

CMS selected 103 kidney transplant hospitals to participate in the IOTA Model for the first performance year. 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").

However, per sections 1835(d) and 1862(a)(3) of the Act as codified in 42 CFR 411.6, Medicare does not pay for services furnished by a Federal provider of services or other Federal agency, nor does Medicare pay for services that are paid for directly or indirectly by a federal government entity, with only limited exceptions. Therefore, CMS is finalizing that eligible kidney transplant hospital criteria will exclude Department of Veteran's Affairs (VA) medical facilities and Military medical treatment facilities (MTFs) from the IOTA Model for PYs 2 through 6.

CMS is finalizing updates to the composite graft survival rate metric that will include the following modifications:

- Adding a modified risk-adjustment framework based on the Scientific Registry of Transplant Recipients' (SRTR's) risk adjustment methodology for the 1-year graft survival metric.
- Excluding multi-organ transplants from the composite graft survival rate exclusion and inclusion criteria, in recognition of their more complicated results for kidney transplant recipients.
- Updating the allocation of points awarded for performance on the composite graft survival rate.

As finalized in the 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.

Questions? Contact Andrew Wheeler, MHA's Vice President of Federal Finance, at 573-893-3700 | ext. 136 or awheeler@MoHospitals.org

4712 Country Club Drive, Jefferson City, Mo. 65109
P.O. Box 60, Jefferson City, Mo. 65102
573-893-3700 | MoHospitals.org
MHA
MISSOURI HOSPITAL ASSOCIATION

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.

As finalized in section II.B.3.c.(2), if full payment for a downside risk adjustment payment is not received by CMS within 60 days after demand is made, the remaining amount owed will be considered a delinquent debt.

Key changes include;

- **Participant Eligibility**
  - VA and Military treatment facilities are **excluded** from the model (Medicare doesn't pay for their services).
  - The minimum transplant volume threshold is **raised from 11 to 15** kidney transplants per year to be eligible.
- **Performance Assessment (Quality)**
  - **A risk-adjustment methodology** (based on SRTR's framework) is added to the composite graft survival rate metric to account for donor/recipient complexity.
  - Multi-organ transplants are **excluded** from the composite graft survival calculation.
  - The points awarded for performance are updated.
- **Payment Structure**
  - **Medicare Advantage (MA) beneficiaries** are now included in upside and downside risk payment calculations (previously only Medicare FFS).
  - The maximum upside payment of **$15,000 per transplant** is retained (a proposed cut to $10,000 was dropped after stakeholder pushback).
  - Downside risk payments must now be remitted **within** 60 days of a demand letter (not "at least 60 days after").
- **Extreme and Uncontrollable Circumstances (EUC)**
  - CMS retains the Quality Payment Program definition of EUC.
  - CMS gains discretion to **adjust both the direction and magnitude** of upside or downside payments when an EUC is declared.
- **Transparency & Patient Notification**
  - Hospitals must publicly post **waitlist selection criteria** and **living donor selection criteria** on their websites.
  - New requirement: notify Medicare beneficiaries **within 10 days** when their waitlist status changes from active to inactive, with annual reminders.
  - Patients must be given the opportunity to **decline** organ offer acceptance criteria reviews.
- **Compliance & Termination**
  - Added monitoring obligations tied to the new transparency requirements.
  - Expanded grounds for termination to include Organ Procurement and Transplantation Network (OPTN).

- OPTN policy violations and False Claims Act actions. Organ Procurement and Transplantation Network (OPTN)

Comments

In what has become standard for CMS, there is no table of contents (ToC). Once again, using AI and the rule itself, we have constructed the following ToC (below).

Please note there are 2 Section II, 3 items titled "3." Further, Section II, B, 2 has a subsection "a" but there is no "b."

CMS estimates that as a result of the finalized changes to the IOTA Model, net Federal savings will increase by $60 million.

Table of Contents

I. Background and Executive Summary

A. Model Overview and Background Page 1

B. Executive Summary Purpose Page 2

1. Purpose Page 2

2. Summary of the Major Provisions Page 3

a. IOTA Participants Page 3

performance Assessment Page 4

c. Payment Page 5

d. Other Requirements Page 8

1. Transparency Page 8

2. Health Equity Plans Page 10

e. Beneficiary Protections Page 10

f. Monitoring Page 11

g. Termination Page 11

3. Summary of Costs and Benefits Page 12

II. Changes to the Increasing Organ Transplant Access (IOTA) Model Page 12

A. Background Page 12

1. Purpose Page 12

2. Statutory Authority and Background Page 13

B. Provisions of the Proposed Regulation Page 15

1. IOTA Participants Page 15

a. Background Page 15

b. Mandatory Participation Page 16

2. Performance Assessment Page 26

a. Method and Scoring Overview Page 26

b. Quality Domain Page 27

1. Background Page 27

2. Post-Transplant Outcomes Page 27

(a) Calculation of Metric Page 27

3. Payment Page 85

a. Background Page 85

b. Alternative Payment Design Page 86

c. Downside Risk Payment Modifications Page 85

1. Background Page 85

2. Alternative Payment Design Page 86

c. Performance-Based Payment Method Page 101

1. Determine Final Performance Score Range Category Page 101

2. Downside Risk Payment Page 103

3. Extreme and Uncontrollable Circumstances (EUC) Policy Page 105

4. Other Requirements Page 109

a. Transparency Page 109

1. Publicly Posted Patient Selection Waitlist Criteria Page 109

2. Public Reporting of Waitlist and Living Donor Selection Criteria Page 123
3. Transparency into Kidney Transplant Organ Offers Page 129
4. Review of Acceptance Criteria Page 151
5. Waitlist Status Change Notification Page 161
b. Health Equity Plans (Removal) Page 213
5. Beneficiary Protections Page 221
a. Background Page 221
b. Beneficiary Notifications Page 222
6. Monitoring Page 224
7. Remedial Action and Termination Page 226
8. Technical Corrections Page 229
C. Requests for Information (RFIs) on Topics Relevant to the IOTA Model Page Page 229
1. Pre-Transplantation Access Process Measure Page 229
2. Allocation Out-of-Sequence (AOOS) Page 230

III. Collection of Information Requirements Page 231

IV. Regulatory Impact Analysis Page 231
A. Statement of Need Page 231
B. Overall Impact Page 232
C. Detailed Economic Analysis Page 233
1. Policy Changes Modeled by Rule Page 233
2. Projected Impact Page 234
3. Net Impact of Final Changes Page 238
4. Estimated Burden on Kidney Transplant Hospitals Page 240
D. Regulatory Review Cost Estimation Page 241
E. Accounting Statement and Table Page 243
F. (Reserved)
G. Regulatory Flexibility Act (RFA) Page 244
H. Unfunded Mandates Reform Act (UMRA) Page 246

I. Federalism Page 246

J. E.O. 14192, "Unleashing Prosperity Through Deregulation" Page 246

Regulatory Text Amendments (42 CFR Part 512) Page 247

Calculation of Metric Page 27

CMS spends nearly 50 pages describing its finalized provisions for calculating the composite graft survival rate at § 512.428(b)(1).

Below, is CMS' hierarchical logistic Scientific Registry of Transplant Recipients (SRTR) regression statistical model. Page 38

Equation 1: Considered Hierarchical Logistic Regression Equation

$$logit\ Pij =$$

$$\beta_0 + \beta_1(Age_ij) + \beta_2(Diabetes_ij) + \beta_3(DialysisVintage_ij) +$$

$$\beta_4(KDPI_ij) + \beta_5(DCD_ij) + \beta_6(PRA_ij) + u_j$$

$Where$:

$- Pij$

$= probability\ of\ graft\ survival\ for\ kidney\ transplant\ patient\ i\ in\ IOTA\ participant\ j$

$- uj \sim N\ \mathbf{0}, \sigma\mathbf{2}$

$u\ represents\ random\ IOTA\ participant - level\ effects$

$- \beta\mathbf{0} = intercept$

$- \beta\mathbf{1} - \beta\mathbf{6} = fixed\ effect\ coefficients\ for\ risk\ adjustment\ variables$

CMS says that "many commenters urged CMS to adopt the existing SRTR risk-adjustment

methodology rather than developing a separate approach for the IOTA Model, citing concerns that the proposed risk-adjustment methodology lacked sufficient clinical input and validation, may be complex to implement, could incentivize risk-averse behavior, and may not meaningfully affect a cumulative measure over time while potentially failing to keep pace with evolving clinical practice."

CMS is finalizing an updated risk-adjustment methodology in the calculation of the composite graft survival rate (see Equation 2), where the observed composite graft survival rate is the IOTA participant's actual composite graft survival rate, as finalized in Equation 1 to Paragraph (b)(1) at § 512.428, with a "Bayesian" adjustment applied for statistical reliability.

Equation 2: Observed Composite Graft Survival Rate

$$\mathit{Composite\ Graft\ Suvival\ Rate}_{\mathit{Observed\ Adjusted}} = \frac{\#\ \mathit{of\ Functioning\ Grafts} + 2}{\mathit{Total\ Completed\ Transplants} + 2}$$

Page 45

Next, CMS would calculate the risk score for each IOTA participant using the following equation (see Equation 3), which is a ratio that quantifies each IOTA participant's risk of graft failure relative to the national graft failure rate. It compares each IOTA participant's expected graft failure rate to the national graft failure rate. Page 46

Equation 3: Risk Score Equation

$$\mathit{Risk\ Score} = \frac{\mathit{Expected\ Graft\ Failure\ Rate}_{\mathit{IOTA\ Participant}}}{\mathit{Graft\ Failure\ Rate}_{\mathit{National}}}$$

Equation 4: Expected Graft Failure Rate.

$$Prob(failure) = 1 - S0(t)exp(\beta X)$$

Questions? Contact Andrew Wheeler, MHA's Vice President of Federal Finance, at 573-893-3700 | ext. 136 or awheeler@MoHospitals.org

4712 Country Club Drive, Jefferson City, Mo. 65109
P.O. Box 60, Jefferson City, Mo. 65102
573-893-3700 | MoHospitals.org

MHA MISSOURI HOSPITAL ASSOCIATION

To calculate the expected graft failure rate needed for the risk score, CMS would use SRTR's adult kidney graft survival first-year, post-transplant risk-adjustment models for both deceased donor and living donor kidney transplants51 which employs a Cox proportional hazards regression model to perform a time-to-event (TTE) analysis (see Equation 4).

The risk score would be normalized to provide a national mean of 1.0. Page 49

Equation 5: National Graft Failure Rate.

$National\ Average\ Graft\ Failure\ Rate =$

$Number\ of\ Graft\ Failures$

$Number\ of\ Completed\ Kidney\ Transplants$

Lastly, the risk-adjusted composite graft survival rate for an IOTA participant would be calculated by multiplying its observed composite graft survival rate by a calculated risk score (see Equation 6).

Page 49

Equation 6: Composite Graft Survival Rate Risk-Adjusted

$Composite\ Graft\ Suvival\ RateRsk\ Adj$

$= Composite\ Graft\ Survival\ RateObserved\ Adjusted\ x\ Risk\ Score$

Comment

As some commentators have noted, these formulas are indeed complex and appear very difficult to implement.

One has to ask is this truly aimed at improving quality or simply decreasing Medicare spending.

Questions? Contact Andrew Wheeler, MHA's Vice President of Federal Finance, at 573-893-3700 | ext. 136 or awheeler@MoHospitals.org

4712 Country Club Drive, Jefferson City, Mo. 65109
P.O. Box 60, Jefferson City, Mo. 65102
573-893-3700 | MoHospitals.org

MHA MISSOURI HOSPITAL ASSOCIATION

Calculation of Points Page 76

CMS is finalizing, with modification, to paragraph (d) at § 512.428, to reflect the updated points allocation, as outlined in the table below, such that IOTA participants that perform: Page 83

Composite Graft Survival Rate Scoring

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
87.5th percentile	Equals 87.5th percentile	Greater than 87.5th percentile	20
75th percentile	Equals 75th percentile	Less than 87.5th percentile	18
62.5th percentile	Equals 62.5th percentile	Less than 75th percentile	15
50th percentile	Equals 50th percentile	Less than 62.5th percentile	13
37.5th percentile	Equals 37.5th percentile	Less than 50th percentile	10
25th percentile	Equals 25th percentile	Less than 37.5th percentile	8
12.5th percentile	Equals 12.5th percentile	Less than 25th percentile	5
12.5th percentile	N/A	Less than 12.5th percentile	0

Payment Page 85

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.

Rather than lowering to the maximum upside risk payment allotment per Medicare kidney transplant to $10,000, as considered in section II.B.3.b. of the 2025 Proposed Rule, the maximum upside risk payment per Medicare kidney transplant will remain at $15,000.

CMS is finalizing its proposals to clarify the appropriate final performance score ranges for an IOTA participant to be eligible to receive an upside risk payment, be in the neutral zone, or receive a downside risk payment at § 512.430(b)(1), (b)(2)(ii), and (b)(3)(i) without modification, as illustrated in the table below. Page 102

Updated Performance-Based Payments by Final Performance Score

Final Performance Score	PY 1	PY 2 – 6
61-100	Upside Risk Payment	Upside Risk Payment
40-60 (Inclusive)	Neutral Zone	Neutral Zone
0 - 39	Neutral Zone	Downside Risk Payment

Final Thoughts and Comments

This is another rule that relies on repeating much from prior rulemaking.

Using Adobe Acrobat's word search feature, the use of saying thanks to commenters is repeated some 99 times, and the word appreciate appears nearly 50 times. Rule's would become simpler if CMS did not find it necessary to say these messages over and over.

CMS says the inclusion of MA beneficiaries accounts for growth in MA, mitigates variation in geographic MA penetration, and increases savings to the Medicare trust fund. Once more, are the savings the real objective of this rulemaking.

Overall, CMS says mean net savings total $88 million over 6 years, ranging from a savings of $246 million to a cost of $52 million at the 10th and 90th percentiles, respectively.

Projected Impact of Upside/Downside Risk Payments, Kidney Transplants, and Net Federal Spending 2026 Final Rule

							6 Year Totals		
	7/1/25-6/30/26	7/1/26-6/30/27	7/1/27-6/30/28	7/1/28-6/30/29	7/1/29-6/30/30	7/1/30-6/30/31	Mean	10th Percentile	90th Percentile
Upside Risk Payments	16	20	23	26	24	26	135	104	168

Downside Risk Payments	0	-1	-1	-1	0	-1	-3	-4	-2
Total Net Payments	16	19	22	25	24	26	133	101	165
Added Transplants	208	442	704	986	1,184	1,243	4,766	2,055	7,708
Impact on Federal Spending	-8	-18	-31	-45	-57	-62	-221	-246	-78
Mean Net Savings	8	1	-8	-20	-33	-37	-88	-246	52

CMS says the cost of reviewing the rule for each commenter would be $132.44 [1 hour to review the rule.] I would like to know if anyone can review 260 pages in an hour. Page 242