CLIENT ALERTS & INSIGHTS

CMS's IOTA Model Took Effect July 1, 2025: Implications for Transplant Hospitals and Nephrology Stakeholders

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Key Takeaways:

- On July 1, 2025, CMS launched the mandatory Increasing Organ Transplant Access (IOTA) Model, requiring about 100 randomly selected kidney transplant hospitals to participate in a six-year program that ties financial incentives and penalties to their transplant performance, efficiency and quality. The model also introduces a new collaborator framework, allowing collaborators to share incentives, which may include nephrologists, other physician specialties, group practices, therapists, PT and non-physician providers, plus dialysis facilities, SNFs, LTCHs, rehab facilities, PT, HHAs and CAHs.
- The IOTA Model fundamentally changes how transplant hospitals and nephrology practices are held accountable and rewarded, embedding financial risk and opportunity directly at the hospital level, increasing compliance complexity and introducing new contractual and operational risks. Failure to comply with payment caps, documentation and non-duplication rules could result in financial penalties or loss of incentives.
- Proactive planning and ongoing monitoring are essential to maximize incentives, avoid penalties and adapt to the evolving CMS kidney care landscape. Hospitals and nephrology practices should immediately review and update their contracts to address new gainsharing caps, document allocation methods and ensure compliance with anti-referral rules. They must also establish robust systems for tracking patient attribution, financial reconciliations and compliance with both IOTA and CKCC requirements.

On July 1, 2025, the Centers for Medicare & Medicaid Services ("CMS"), through its Center for Medicare & Medicaid Innovation ("CMMI"), launched the Increasing Organ Transplant Access ("IOTA") Model. This six-year mandatory demonstration will continue through June 30, 2031, and is designed to test whether performance-based incentive payments for kidney transplant hospitals can expand access to transplantation while preserving or enhancing quality of care and reducing Medicare expenditures.[1]

Participation is not voluntary. CMS randomly selected approximately half of all eligible kidney transplant hospitals ("Transplant Hospitals")- about one hundred in total - across organ procurement designated areas to ensure geographic and demographic diversity. Hospitals with fewer than eleven adult kidney transplants in each baseline year or pediatric transplant facilities were excluded from selection.[2]

Participation is mandatory to minimize the potential for selection bias and to ensure an adequate sample size.

Unlike prior kidney models, IOTA directly embeds accountability at the hospital level while also creating a defined role for "collaborators"-nephrologists, physician group practices, dialysis facilities and certain post-acute providers-to share in model incentives.

Performance Domains and Scoring

Transplant Hospitals are assessed annually across three domains: achievement (up to 60 points), efficiency (up to 20 points) and quality (up to 20 points).

- **Achievement.** Transplant Hospital targets are customized to each hospital, calculated by averaging each Transplant Hospital's adult kidney transplant volume (both living and deceased donor) from baseline years and trending forward using the national growth rate. If the national growth rate is negative, a zero-growth rate is applied.
- **Efficiency.** Efficiency is assessed using the kidney organ offer acceptance rate ratio, which compares each Transplant Hospital's acceptance of offered kidneys to expected acceptance rates, with scoring based on national benchmarks or improvement against the Transplant Hospital's prior performance. CMS will pick the method which results in the most points.
- **Quality.** Quality is measured by a composite graft survival ratio, and Transplant Hospitals may also submit voluntary Health Equity Plans addressing disparities around transplantation.[3]

Performance Years ("PYs") run July 1 through June 30. PY1 (July 1, 2025-June 30, 2026) is upside-only, with no downside obligation. From PY2 onward, scoring determines financial adjustments: hospitals with scores of 60 or above may earn up to $15,000 per transplant; those scoring 41-59 enter a neutral zone where no payment is received or owed; and those scoring 40 or fewer face downside obligations of up to $2,000 per transplant.

This neutral zone was introduced to mitigate volatility and stabilize financial exposure for Transplant Hospitals near performance thresholds.

Attribution and Beneficiary Rules

Attribution of patients to Transplant Hospitals under IOTA is both monthly and dual-tracked. Waitlisted patients age 18 or older are attributed to every Transplant Hospital at which they are registered during each month of registration. Transplant patients are attributed exclusively to the Transplant Hospital that performs the transplant.

This attribution system means that a patient may simultaneously be attributed to multiple Transplant Hospitals while waitlisted, but once a transplant is performed, attribution is fixed to the performing Transplant Hospital. This dual approach is intended to encourage Transplant Hospitals to both expand waitlists and increase successful transplants.

CMS provides Transplant Hospitals with beneficiary-identifiable claims data (subject to HIPAA data-use agreements) and aggregate/de-identified data for benchmarking. Transplant Hospitals

must also publish waitlist criteria on public websites, notify attributed patients of IOTA participation, and review organ offer acceptance criteria with IOTA waitlisted Medicare patients every six months.

IOTA additionally authorizes Transplant Hospitals to furnish certain patient engagement incentives-including transportation assistance, communication devices, in-home support, mental health services and immunosuppressive drug cost-sharing assistance-subject to program rules. This includes submitting a written policy for patient engagement incentives that must be approved in advance by CMS.

CMS has published the full list of IOTA participant hospitals and their associated organ procurement entity designated service area available here.

Collaborator Framework

The collaborator framework is a central innovation of IOTA. Transplant Hospitals who enter into written sharing arrangements with collaborators-including nephrologists, nephrology practices, dialysis facilities and certain post-acute providers-may provide collaborators gainsharing payments when they contribute to the Transplant Hospital's performance. Transplant Hospitals may receive "alignment payments" from collaborators to offset downside losses.

Strict guardrails govern these arrangements. An individual nephrologist or nonphysician practitioner may not receive more than fifty percent of Medicare Physician Fee Schedule ("PFS")-allowed amounts for services provided to attributed patients. A group practice may not receive more than fifty percent of aggregate billings for attributed patients at the TIN level. Hospitals may not receive more than fifty percent of their total downside in alignment payments, nor more than twenty-five percent from any single collaborator.

Collaborator selection must be based on quality criteria and may not directly or indirectly consider the volume or value of referrals. Participants are required to publish collaborator lists, post selection criteria and maintain detailed payment documentation.

Implications for Nephrologists and Practices

For individual transplant nephrologists, eligibility for gainsharing depends on personally furnishing a billable service to an attributed patient, and contribution to performance across the three levels of Transplant Hospital domains, with gainsharing capped at fifty percent of that physician's PFS amounts for those attributed patients during the same program year.

For nephrology practices, eligibility applies at the group level with payments capped at fifty percent of aggregate billings across members for attributed patients.

This distinction has significant contractual implications. Solo nephrologists must ensure their gainsharing is tied directly to their services, while practices must structure agreements to address aggregate caps and internal distributions. Best practices include embedding cap language in contracts, documenting allocation methods and expressly prohibiting referral-based criteria.

Interaction with CKCC

The IOTA Model operates alongside the Comprehensive Kidney Care Contracting ("CKCC") tracks of the Kidney Care Choices ("KCC") Model. CKCC attributes chronic kidney disease and end-stage renal disease patients to Kidney Contracting Entities ("KCEs"), while IOTA attributes waitlist patients and transplant episodes to Transplant Hospitals.

CMS permits dual participation but enforces the non-duplication rule, which prohibits participants from receiving duplicative payments for the same services or beneficiaries. Thus, a transplant episode attributed to a Transplant Hospital under IOTA cannot simultaneously generate CKCC shared savings. Hospitals and practices must therefore maintain separate attribution rosters, ensure independent financial reconciliations and adopt contractual safeguards addressing overlap.

The IOTA Model also incorporates the standard provisions at 42 C.F.R. part 512, which sets forth the requirements for gainsharing arrangements that apply across all Innovation Center models. These include explicit beneficiary protections (attribution does not limit patient choice), compliance and recordkeeping obligations, CMS monitoring and audit authority, remedial action and termination rights, and procedures for reconsideration and appeal.

The interplay between IOTA and CKCC is further shaped by CMS's elimination of the $15,000 CKCC Kidney Transplant Bonus for procedures performed on or after January 1, 2026.[4] CKCC participants will lose this incentive, while IOTA hospitals remain eligible for transplant-based upside payments.

For further detail, see CMS, *Kidney Care Choices (KCC) Model Request for Applications*, https://www.cms.gov/priorities/innovation/files/x/kcc-rfa.pdf.

CMMI Model Realignment

The IOTA Model's launch is part of a broader CMMI realignment, resulting in a significant shift in the innovation models' landscape. In March 2025, CMS announced early termination of the End-Stage Renal Disease Treatment Choices ("ETC") Model, effective December 31, 2025.[5] In May 2025, CMS terminated the Kidney Care First ("KCF") Model and finalized significant revisions to CKCC, including tighter benchmark discounting, reduced chronic kidney disease capitation payments, and elimination of the transplant bonus. At the same time, among other initiatives, CMMI launched the Wasteful and Inappropriate Service Reduction ("WISeR") Model, which deploys artificial intelligence vendors to identify and reduce improper spending, and proposed substantial expansions of Remote Patient Monitoring ("RPM") and Remote Therapeutic Monitoring ("RTM") reimbursement in the CY 2026 Physician Fee Schedule.

Collectively, these actions highlight CMMI's evolving strategy: retire underperforming models, recalibrate existing kidney demonstrations and test scalable, technology-enabled approaches emphasizing fiscal sustainability and equity.

Conclusion

The IOTA Model represents a fundamental shift in federal kidney policy. By embedding transplant accountability at the hospital level and formally incorporating nephrologists and nephrology practices as collaborators, CMS has redefined the incentive structure for transplant care. Hospitals and practices must carefully structure their agreements, monitor compliance with payment caps and referral prohibitions, and manage overlapping obligations with CKCC under the non-duplication rule.

Against a backdrop of terminated and recalibrated kidney models and the rollout of new initiatives such as WISeR and expanded RPM/RTM, the stakes for transplant hospitals and nephrology practices are high. Success in this environment will require careful planning, contractual precision and proactive compliance.

The Benesch Healthcare+ team is monitoring these developments closely. Please contact the authors of this article for further guidance tailored to your organization.

[1] *Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model,* 89 Fed. Reg. 96,280 (Dec. 4, 2024), https://www.federalregister.gov/documents/2024/12/04/2024-27841.

[2] *IOTA Final Rule*; Ctrs. for Medicare & Medicaid Servs., *Increasing Organ Transplant Access (IOTA) Model Frequently Asked Questions* (Aug. 28, 2025), https://www.cms.gov/priorities/innovation/innovation-models/increasing-organ-transplant-access-model/fa
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[3] Initially introduced as a mandatory requirement in the proposed rule starting in Y2, Health Equity Plans are now voluntary for all 6 program years. While addressing discrepancies in kidney transplantation for Transplant Hospitals, there is no fiscal or numerical advantage in devising and submitting a Health Equity Plan to CMS related to the performance and scoring under IOTA.

[4] *CMS Terminates Kidney Care First (KCF) Model and Finalizes Significant Revisions to CKCC Participation and Payment Framework* (May 28, 2025), https://www.beneschlaw.com/publication/cms-terminates-kcf-model-and-finalizes-significant-revisions-to-
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[5] *CMS Announces Early Termination of the ESRD Treatment Choices (ETC) Model* (Mar. 14, 2025), https://www.beneschlaw.com/resources/cms-announces-early-termination-of-the-esrd-treatment-choices-