



VIA ELECTRONIC FILING — <https://www.regulations.gov/>

February 5, 2026

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244-8016

Re: CMS-5544-P Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model

Dear Dr. Oz:

United Network for Organ Sharing (UNOS) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed updates to the Increasing Organ Transplant Access (IOTA) Model under **File Code CMS-5544-P**, published in the Federal Register on December 11, 2025. UNOS has more than forty years of experience supporting organ donation and transplant in the United States as a contractor serving the Organ Procurement and Transplantation Network (OPTN).

For decades, UNOS has worked with the federal government and community stakeholders to increase transplants and strengthen the system for organ donors, patients, and their families. Our comments reflect UNOS's commitment to data stewardship, efficiency, transparency, and continuous improvement, and build upon our July 2024 response to CMS' earlier IOTA Proposed Rule notice, published in May 2024.

UNOS continues to support CMS' goals of increasing kidney transplantation, strengthening transparency, encouraging living donation, and improving fairness in access to transplant. Our dedication to supporting the community through the success of the IOTA model is demonstrated in our recent development of an IOTA specific dashboard currently available to all kidney transplant hospitals. To date, more than 150 hospitals have accessed this product. This tool allows hospitals to monitor their progress weekly on all three of the IOTA outcomes (Achievement, Efficiency, and Quality).

Our comments focus on areas where we believe alignment with existing OPTN and transplant community workflows will materially improve the IOTA model's success.

Recommendation: Leverage Existing Processes to Deliver Transparency to Patients

Proposals within the IOTA model and program regarding transparency would require complex participant-specific reporting, particularly semiannual declined-offer notifications and waitlist status changes. UNOS agrees that these proposed changes would help create system transparency. We caution that individualizing these functions across one hundred hospitals risks duplicating work and could create reporting variances that confuse critical data interpretation.

We support CMS' goal of ensuring patients are promptly notified of changes that impact their eligibility for organ offers. Making organ-offer information and waitlist status changes available to patients can empower them to participate actively in their care. At the same time, transparency must be operationally feasible and delivered in a way that patients can understand and apply.

Several CMS transparency requirements, including declined-offer notifications and waitlist status changes, hinge on accurate identification of CMS-attributed beneficiaries. While the proposed content within the notification is appropriate, CMS should ensure hospitals are not required to recreate information already captured within OPTN systems.

To operationalize CMS' proposed transparency requirements efficiently, CMS could securely transmit attribution lists to the OPTN, enabling the following:

- Automated generation of patient-specific standard reports for each Medicare beneficiary for all hospitals including organ-offer decline summaries and waitlist status changes
- Reductions in manual reconciliation by hospitals
- Standardized formatting of CMS-required notifications

This approach would improve accuracy and dramatically reduce the administrative burden of consolidating the patient-specific standard reports included in the proposed transparency requirements for both hospitals and CMS. However, the creation of standardized reports by the OPTN alone would not eliminate the burden on individual hospitals of developing a process for the distribution of these reports to individual patients. To further reduce burden on hospitals, these reports could be delivered to CMS for distribution to patients, or the OPTN could enlist a contractor to create a secure patient portal for transplant patients to access these reports along with accompanying educational documents.

UNOS is ready and willing to collaborate with CMS to leverage our decades of expertise with OPTN data reporting to provide these standardized reports of patient status changes and organ offers. We recommend CMS work to create collaborative opportunities with members of the OPTN and its contractors that allow access to the patient-level data of Medicare patients. This approach would align with HRSA's goals of improving data collection to improve performance monitoring, while engaging patients and families to answer questions and share data.

Usage of standardized reports and centralized distribution will reduce the burden on hospital staff by ensuring consistency; reduce variation in report formats; minimize interpretive burden for patients; and standardize data for improved performance monitoring in alignment with CMS' requirements. This approach will promote consistent implementation of CMS's stated goals of increasing transplant volume (Achievement), improving organ acceptance practices (Efficiency), and maintaining quality outcomes post-transplant (Quality).

Due to the fact all transplant hospitals already have access to a multitude of patient-specific OPTN data reports, CMS' transparency goals could be achieved with greatly reduced burden if CMS collaborates with the OPTN to develop standardized reports for patients and identify a plan for centralized distribution of the reports. This collaboration will ensure compliance with plain-language expectations, consistency across hospitals, and reduced staff burden.

Recommendation: Risk-Adjusted Graft Survival Rate Should be Transparent

UNOS supports CMS' proposal to incorporate a risk-adjusted composite graft survival rate. We recommend the following:

- **Robust risk adjustment for the Graft Survival Rate metric is essential.** Risk adjustment is necessary not only for fairness, but also to ensure that the IOTA model does not inadvertently disincentivize transplantation for medically complex candidates or use of less ideal deceased donor kidneys.
- **Increased transparency into the modeling methodology.** We recommend CMS provide full visibility into the modeling approach, variable selection, weighting, and updated cadence. Without transparency, participants cannot meaningfully monitor or improve performance, and patients cannot understand what factors affect outcomes.

- **Alignment with SRTR's risk-adjustment framework.** The Scientific Registry of Transplant Recipients (SRTR) methodology is well-validated, widely understood, and already integrated into transplant center reporting and outcomes monitoring. We recommend CMS adopt or closely align with SRTR's approach, which would promote consistency and support interoperability with existing tools.
- **Reevaluation of Graft Survival.** UNOS recommends CMS reconsider the appropriate metric for measuring graft survival. Currently, CMS proposes a risk-adjusted composite graft survival rate. Instead of using a composite graft survival rate, UNOS believes that a one-year or three-year survival rate at a defined time point would be a more effective measure of graft success and better align with CMS' goal of improving transparency. One-year survival, unlike a composite graft survival rate, provides patients and providers a clear and interpretable expectation for graft success at a defined time point after transplant than when risk adjusted, and is comparable across patients and centers. Additionally, this recommendation aligns with SRTR's risk adjustment framework and historical monitoring of graft success by the OPTN and payors.

Mandatory Participation Criteria and Monitoring Requirements

UNOS supports raising the low-volume threshold from 11 to 15 transplants, but CMS should provide clarifications about the impact on access in less populous regions. Further, we support CMS' proposed exclusion of the Department of Veterans Affairs (VA) and Medical Treatment Facilities (MTF) from Performance Years 2-6.

Conclusion

UNOS supports CMS' efforts to advance kidney transplantation through the IOTA Model and appreciates the Agency's attention to transparency, equity, and data-driven program evaluation. UNOS's recommendations about model transparency and reporting standardization focus on a CMS collaboration with the OPTN to minimize hospital resources required to support success.

In partnership with the OPTN, we encourage CMS to leverage existing infrastructure to provide data and reporting capabilities to:

- Minimize administrative burden
- Strengthen national consistency in reporting to patients
- Improve patient-centered transparency
- Support high-quality data interpretation
- Enable hospitals to monitor and respond to IOTA Model requirements effectively

Thank you for the opportunity to comment with our recommendations for the success of the IOTA Model and to strengthen the national organ donation and transplant system.

Sincerely,

Alicia Hennie

Alicia Hennie
Vice President, External Affairs
United Network for Organ Sharing