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CMS Proposes New Payment Model for Some Kidney Transplant Programs

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In its continuing efforts to improve the organ donation and transplant system and promote health equity, the U.S. Department of Health and Human Services (HHS), acting through the Centers for Medicare and Medicaid Services (CMS), announced proposed revisions to 42 CFR Part 512, which would establish the Increasing Organ Transplant Access (IOTA) Model. The IOTA Model aims to test whether performance-based incentive payments to selected kidney transplant hospitals would increase access to kidney transplants for people living with end-stage renal disease (ESRD), improve the quality of care for people seeking kidney transplants, reduce disparities among individuals undergoing the process to receive a kidney transplant and increase efficiency and capacity.

Are all kidney transplant programs impacted?

No. Importantly, the IOTA Model would only affect kidney transplant hospitals that, during each year of a three-year historical baseline period: 1) performed 11 or more transplants for patients 18 or older; and 2) transplanted greater than 50 percent of their total kidney transplants to patients over age 18. CMS will select approximately half of all donation service areas (DSAs) nationwide using a stratified random sampling methodology, and all eligible kidney transplant hospitals in those DSAs will be *required* to participate in the IOTA Model. CMS estimates that 90 out of the 257 transplant hospitals in the country will be required to participate.

When would the IOTA Model take effect?

As proposed, each of the six years beginning January 1, 2025, through December 31, 2030, would constitute a performance year for purposes of evaluation under the new performance metrics. The standard provisions in the proposed rule would be applicable to all participating programs on/after January 1, 2025.

How will performance be measured?

New performance metrics will serve as the basis for the proposed incentive payments, with three categories assigned a score totaling 100 possible points. The categories and breakdown of points are as follows:

- Achievement (60 points). The number of adult kidney transplants (based on performance against a historical target) with a health equity performance adjustment. This metric is based on a historical volume of deceased and living donor transplants furnished to attributed patients in the relevant baseline years, adjusted by the national trend rate in the number of kidney transplants performed, and further adjusted by the proportion of transplants furnished to attributed patients who are low income.

- Efficiency (20 points). Organ offer acceptance rate ratio. This metric is based on the number of kidneys a participant accepts for transplant over the expected value, based on variables such as kidney quality.

- Quality (20 points). Post-transplant composite graft survival rate; colorectal cancer screening; and certain patient measures related to discharge care and collaborative decision making.

How will performance payments work?

Each performance year, a participating kidney transplant hospital will fall into one of three categories based on their final score as follows:

- Final score of 60 or greater: Hospitals will receive a lump sum upside risk payment from CMS equal to the final performance score minus 60, then divided by 60, then multiplied by $8,000, then multiplied by the number of kidney transplants to attributed patients with Medicare as their primary or secondary payer during the performance year.
  - For example, a hospital that performed 150 qualifying kidney transplants and received a final score of 85 would receive a $500,000 lump sum payment under the proposed incentive calculus.
- Final score between 41 and 59: Hospitals in this performance range will be considered neutral and will not receive any lump sum payments or be required to make any payments to CMS.
- Final score of 40 or lower: Hospitals will owe CMS a lump sum downside risk payment equal to the participant's final performance score minus 40, then divided by 40, then multiplied by -$2,000, then multiplied by the number of kidney transplants to attributed patients with Medicare as their primary or secondary payer during the performance year.
  - For example, a hospital that performed 150 qualifying kidney transplants and received a final score of 35 would owe CMS $37,500.
  - Downside risk payments will be required only after the second performance year.

Other provisions in the proposed rule

In addition to creating the IOTA Model, the proposed rule contains provisions related to the following:

- Data collection and sharing;
- Transparency;
- Public reporting;
- Health equity plans;
- Medicare payment waivers and additional flexibilities; and
- Monitoring.

Key Takeaways and Next Steps

The proposed rule appears to align with the goals of the Organ Transplantation Affinity Group (OTAG), which launched last fall as a collaboration between HRSA and CMS and aims to improve transplantation system equity and performance. As a threshold matter, it is worth considering whether a performance-based payment model with a "carrot and stick" approach is an appropriate way to address equity concerns and improve patient outcomes. Proposing financial incentives may make sense if the barriers to better kidney utilization and equitable access stem from a transplant hospital's increase in costs related to the utilization of less-than-perfect kidneys, but there are many other systemic factors driving disparities in access and outcomes.

Additionally, OPOs that work with participating transplant centers may see increases in their transplant rate. For example, an organ procurement organization (OPO) that supplies recovered kidneys to a participating transplant program may see its CMS performance measures improve because OPO performance is, in part, measured by organs that are actually transplanted. However, given the broader organ-sharing rules, most

OPOs should be able to work with participating transplant centers to increase the number of kidneys transplanted.

Interested parties can provide comments to CMS on these and other considerations during the proposed rule's public comment period. CMS has also issued a related request for information on the following topics: patient-reported outcome performance measures; how to appropriately measure access to the kidney transplant waitlist; how to improve interoperability of software systems and tools used to manage chronic kidney disease, ESRD, and kidney transplant patients; and the feasibility of requiring IOTA participants to conduct health-related social needs screenings for at last three core areas – food security, housing, and transportation.

The public comment period will run from the date of the proposed rule's publication – May 17, 2024 – through July 16, 2024.

For more information, please contact Melodie Hengerer, Tenia Clayton, or any member of the Baker Donelson Health Law Team.