Cleveland Clinic

July 16, 2024

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5535-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-5535-P – IOTA Proposed model

Submitted via: Regulations.gov

Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching, and research. With a footprint in Northeast Ohio, Florida, and Nevada, Cleveland Clinic Health System operates 23 hospitals, including a main campus near downtown Cleveland, with more than 6,690 beds, and 276 outpatient locations. Cleveland Clinic employs over 5,700 physicians and researchers, and 16,500 nurses. Last year, our system had 15.1 million patient encounters, including 13.7 million outpatient visits and 323,000 hospital admissions and observations.

Cleveland Clinic supports the health care system moving toward the provision of more accountable, coordinated care. As such, we have a long track record of volunteering for Medicare's initiatives to increase value and better serve patients. For example, our Cleveland Clinic Medicare Accountable Care Organization (CCMACO) is in its third agreement period in the Medicare Shared Savings Program (MSSP); we also participate – or have participated in – models that include Primary Care First; Comprehensive Primary Care Plus; the Bundled Payments for Care Improvement Advanced (BPCI-A) model; Oncology Care Model; and the Independence at Home demonstration. We also have participated in the Comprehensive Care for Joint Replacement (CJR) mandatory model.

Cleveland Clinic is one of the leading centers in the nation for kidney transplantation, with more than 3,000 transplants performed since 1963. We have a multidisciplinary team of experts who provide comprehensive and personalized care for patients with end-stage renal disease, including pre-transplant evaluation, surgical management, post-transplant follow-up, and long-term support. Our outcomes are among the best in the country; our center performed above the national average in both patient and graft survival rates for kidney transplants in the year 2024. Our one-year graft survival rate was 95.3% compared to the US average of 94.54% and our one-year patient survival rate of was 97.14%, compared to the US average of 96.75%. We also offer innovative techniques such as living donor kidney exchange, laparoscopic donor nephrectomy, and robotic-assisted kidney transplantation.

We recognize the importance of the Centers for Medicare and Medicaid Services (CMS) goals to transform the health care delivery system in a way that increases access to kidney transplants while preserving or enhancing the quality of care and reducing Medicare expenditures.

However, we have significant concerns that potential unintended consequences driven by the model's incentives could result in outcomes adverse to the agency's stated goals. For example, it appears that the model unintentionally creates incentives to transplant low-risk patients, in opposition to the model's stated goals. Further, the steep increases in transplant volume built into the model – coupled with potential financial penalties – could lead smaller programs to close, creating access issues for patients. Finally, the model's incentives to increase transplant volumes may create a distortion in the organ allocation system as participating hospitals must increasingly compete for scare organs. Coupled with the significant amount of uncertainty with the changes occurring at HHS to reimagine how the transplant system is currently organized, this model could further disrupt the existing transplant system amidst ongoing debates regarding organ distribution. **Because of these significant concerns and the potential that even voluntary participation by a subset of transplant hospitals could lead to unintended impacts on the allocation of scarce organs, we urge CMS to refrain from finalizing this model. Further, we urge that any future efforts to impact transplant access through payment incentives be informed by significant stakeholder feedback throughout model development.** Below is our detailed feedback on specific aspects of the proposed model.

MODEL PERFORMANCE PERIOD

CMS proposes that this mandatory model would begin Jan. 1, 2025, and further that it will notify selected transplant hospitals at least three months before the start date. While the agency notes that it considered later start dates, it ultimately concluded that concluded that this timeline will give participants sufficient time to prepare for the model. We believe that CMS has not adequately accounted for the financial and operational complexities associated with preparing for performance in a value-based model, particularly a mandatory model that ultimately includes downside risk. In particular, the steep volume increases CMS has built into the model would require additional resources to achieve; the agency's proposed timeline provides no time for selected hospitals to budget for these resources or to hire and train additional staff (particularly the care team, who require a highly-specialized skill set); procure any needed additional equipment; secure any additional room capacity necessary; and develop the analytical infrastructure necessary to support model participation. This would require selected transplant programs to essentially build the plane while it's in flight, which does not set them up for successful performance even given there being no downside financial risk in the first year. Even CMS's proposed mandatory bundled payment model, which is substantially similar to other models the agency has offered, would provide more lead time for selected hospitals. **If CMS does move forward with this model, we urge a start date of no earlier than Jan. 1, 2026.**

IOTA PERFORMANCE ASSESSMENT

CMS proposes to assess participants across three performance domains – achievement, efficiency and quality – to calculate a performance score that will be used to determine whether participants receive any payment or owe a downside risk payment to CMS. We are generally uncomfortable with the proposed metrics, as some of them lack scientific validation from the transplant community, and they are not risk-adjusted which is crucial for ensuring their reliability. In addition, because transplants occur with less frequency compared to more common procedures (e.g. colonoscopies), a single or even a few adverse scores will disproportionately affect a participating program's overall score, potentially exposing them to the risk of incurring a penalty.

If CMS decides to move forward with this model, we recommend metrics used by the Scientific Registry of Transplant Recipients (SRTR) to evaluate US transplant programs, as these metrics are both validated in the special practice of transplantation and risk adjusted. The SRTR offers a

comprehensive set of data analyses and program-specific reports that can provide valuable insights into transplant program performance and patient outcomes. By leveraging SRTR's robust metrics, CMS can ensure a data-driven approach to assess the effectiveness of the IOTA model, ultimately aiming to improve patient results and experiences in the transplant process.

Achievement Domain:

CMS proposes to measure participants on the number of kidney transplants performed on adults 18 years and older compared to a historical target, subject to a health equity adjustment intended to incentivize participants to decrease disparities in the overall transplant rate for low-income and underserved patients. **While we agree with the agency's goal to increase the number of transplants, setting a target to increase organ transplant rates by 25 or 50 percent may not be realistic or achievable within the given constraints and resources, especially for large centers that are already performing at very high levels.** Given that there are a finite number of kidneys available, it is unclear how this considerable growth would be achieved if 50 percent of the programs across the country are attempting to maintain or increase their transplants, with some attempting to increase their transplant target by 50 percent. High-performing centers would enter the model at a distinct disadvantage because increasing their transplant rates even by 25 percent is not realistic given constraints on organs available for transplant. Further, the model does not include any type of strategic initiative to significantly increase donors to grow the supply of organs. The transplant community must manage the organ supply judiciously to meet the needs of those awaiting transplantation, rather than trying to achieve a goal or avoid a penalty.

Based on the current proposed model, to achieve high performance, Cleveland Clinic would be required to increase their annual adult transplant numbers by at least 75 or up to 150 per year. However, the ability to achieve this increase relies on the availability of a sufficient number of viable organs and a significantly increased waitlist. For example, today, Cleveland Clinic has 460 patients on the waitlist with 40% of those inactive, meaning 270 active patients. Even if we added another 270 new patients, with the current statistics, 40% of those will be inactive (this is optimistic as the US average is 50%) so by adding 270 +156 = 426 patients. In the first year, it might be possible for our program to reach this goal, and completely clear our waitlist, but this assumes that every single patient can be transplanted and there are appropriate matches for them, which seems unlikely. Further, any succeeding year, the program would then have a goal that would be unreachable. Mathematically, the only way to continue to meet these ever-rising goals would be to manage a waitlist of nearly 1,000, which is not in the best interests of patients.

Thus, we agree with the conclusion regarding volume targets described in the letter submitted by the American Society of Transplant Surgeons (ASTS). "The proposed volume targets are fundamentally flawed. These targets penalize currently high-performing programs and seem designed to punish participating transplant programs for increasing transplant volumes which will be required to increase transplant volumes more significantly to avoid penalties and are likely to result in significant penalties on the many transplant programs that fall below target performance. This structure may inhibit, rather than encourage, growth in transplant access and volume."

Finally, we are concerned that the 1.2 health equity multiplier will incentivize transplant programs to make patient decisions to improve model performance based on an arbitrary multiplier rather than validated measures that accurately review programs' quality.

Efficiency Domain:

CMS proposes to use the Organ Procurement and Transplantation Network (OPTN) organ offer acceptance rate ratio as the sole measure in the efficiency domain. **We are concerned with this approach because an offer of an organ does not necessarily equate to a viable transplant opportunity.** The model includes no adjustment to account for the scenario where an organ may be deemed non-viable, which can significantly impact the decision-making process in organ transplantation. For example, SRTR uses a methodology in this space that reviews whether any other program accepted the organ. Without this adjustment, an organ procurement organization (OPO) could repeatedly offer a non-viable organ to a variety of programs, all of which would be penalized for non-acceptance.

In the transplant world, maximizing organ utilization sometimes means that an organ must be declined so that it goes to the most appropriate patient who is likely to have the best outcome. However, in this model, a program that declines the organ would be penalized. The decision to accept an organ for a specific patient is a complex analysis, and CMS should rely on validated metrics to measure how offers are considered. An offer of a kidney cannot be viewed in isolation; it is essential to consider the broader context, including other factors and metrics that may influence the decision-making process and potential patient outcomes.

Finally, as mentioned by ASTS in their letter, the inclusion of this measure incentivizes participating programs to focus on deceased donor transplants to increase kidney transplant volume, since the organ acceptance ratio also does not include living donor organs. Living donor organs have superior clinical outcomes and enhanced savings. The IOTA Model should prioritize the living donor and evaluate organ acceptance rather than organ offer as this is more objective and leads to meaningful results.

Quality Domain:

CMS proposes four measures to calculate performance in the quality domain — a post-discharge composite measure reflecting graft survival rates, a shared medical decision-making measure, colorectal cancer screening and a care transition composite measure. We are concerned with the metrics in this domain because as mentioned previously, one or a few adverse scores could significantly affect a program's data. Because the number of transplants carried out is relatively small making meaningful changes or drawing conclusions will be difficult when only a few scores can skew the data so significantly. These widely used quality domains are better suited for use in large populations (e.g. patients in primary care).

Further, the lack of risk adjustment to the grant survival measure means that centers will be incentivized to choose the healthiest patients to transplant and will reject those who are sensitized. Highly sensitized patients have high levels of anti-HLA antibodies, making them more likely to reject a kidney from a donor. These highly sensitized patients are more likely to be African American. In fact, a study published in the Nephrology Dialysis Transplantation journal found that highly sensitized kidney transplant recipients were more frequently African American compared to non-sensitized patients.[1] Thus, failure to risk-adjust this measure could lead to outcomes that run counter to CMS's stated desire to reduce disparities.

[1] Leeaphorn, N., Pena, J. R. A., Thamcharoen, N., Khankin, E. V., Pavlakis, M., & Cardarelli, F. (2018). Pre-transplant donor-specific antibody strength and epitope analysis predict post-transplant outcomes in kidney transplantation. Nephrology Dialysis Transplantation, 33(10), 1797-1805. [URL]

Additionally, as described by ASTS in their letter, this outcome measure imposes on participating transplant programs responsibility for ensuring continuing graft function for a post-transplant period that significantly exceeds the post-transplant period during which transplant programs can reasonably be held accountable for recipients' care. In fact, after the first-year post-transplant, a transplant recipient is typically followed primarily by community nephrologists and other physicians on their healthcare teams who may or may not be associated with the transplant center.

Further, the proposed outcome measure is inconsistent with the primary objective of the IOTA Model to increase transplant volumes and reduce disparities. This proposed measure discourages participating transplant programs from transplanting lower-quality organs, which are significantly less likely to maintain function for six years post-transplant. Therefore, this measure is inconsistent with the fundamental objectives of the IOTA Model to increase the number of transplants performed and to reduce the non-use of lower-quality organs. Additionally, the additional mandate to provide six-year data detracts from what should be an unerring and unwavering focus on increasing transplant volumes.

Finally, no database includes six-year post-transplant graft function data. Finalizing this measure as proposed would impose an extraordinary additional data collection burden on participating transplant programs. The six-year follow-up proposal is not concordant with the preexisting monitoring and reporting framework, and it seems illogical to introduce a significant change, as well as an additional unfunded mandate that is incongruent with the strategic goal of the project.

PAYMENT

CMS proposes that the IOTA model would include both upside and downside risk for Medicare fee-for-service (FFS) payments for kidney transplants. High performance in the model is predicated on sufficient access to adequate organs for transplant; since transplant programs do not drive the supply of organs, they may find themselves categorized as low performance – and thus penalized financially – due to factors outside of their control. This could lead to unintended consequences, the most serious being the shuttering of the smaller transplant programs, which would further limit access for patients. CMS must consider the broader impact of this model and avoid punitive measures that may inadvertently affect the system negatively.

OTHER VALUE-BASED MODELS

In the calendar year 2025 Medicare Inpatient Prospective Payment System proposed rule, CMS proposed a bundled payment model that would be mandatory for selected hospitals. Cleveland Clinic has multiple hospitals that are within the geographic regions eligible for selection. We urge the agency to consider that some hospitals may be subject to selection for both models, potentially imposing significant change on multiple clinical service lines in a short period of time. While the clinical teams dedicated to these models may vary, in our experience they must draw on the same teams to provide support necessary for model performance such as data analytics, quality improvement, etc. Mandated participation in multiple models will stretch hospitals' limited resources even as they continue to struggle with financial headwinds tied to inflationary increases, rising drug costs and staffing shortages – with the potential to ultimately impact their success in these models.

We would welcome the opportunity to discuss our concerns about the model with you. Thank you for considering our perspectives as we strive to enhance the quality and accessibility of care for all.

Sincerely,

Charles Miller, MD
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Director, Transplantation Center