

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

July 16, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244-8016

Re: Proposed Medicare Payment Model: Increasing Organ Transplant Access Model (IOTA Model)

Dear Administrator Brooks-LaSure:

The Organ Procurement and Transplantation Network (OPTN) would like to thank CMS for the opportunity to comment on your proposed rule: Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model (CMS-5535-P). We strongly support the goals of the model, which aim to increase patient access to kidney transplants and maximize the use of deceased donor kidneys. Such goals closely align with several initiatives currently being undertaken by the OPTN, such as the work of the Expeditious Task Force and the development of continuous distribution frameworks.

To best achieve the goals of the model the OPTN recommends a few adjustments to the proposed model before CMS makes the model final.

Unadjusted vs. Adjusted Non-Use Rate

References to the rising non-use rate throughout the proposal pertain to the unadjusted non-use rate, which reflect the number of kidneys recovered for transplant but not ultimately transplanted. The unadjusted rate does not consider differences in donor factors between donor cohorts. Adjusted non-use rates require modeling that adjusts for the effect of ever-evolving donor characteristics. The OPTN recommends CMS use the adjusted non-use rate for the changing donor pool to ensure year-to-year comparisons are made amongst similar groups of donors.

Achievement Domain

As the proposed model currently suggests in *Section III.C.5.c. Achievement Domain*, there is potential for high-performing centers to be benchmarked against their own high past-

performance when evaluating acceptance and volume metrics within the Achievement Domain. We believe that benchmarking high performing centers against the national average for both metrics would be fairer and more accurate when evaluating their performance. The model's intention is to get transplant centers to accept more organs at a greater rate, or increase their organ offer acceptance rate. Organ offer acceptance rates can fluctuate greatly as they are benchmarked against the expectation of which organs would have been used, and which organs would not have been. As transplant programs' willingness to accept a larger range of organs shifts, so will the organ offer acceptance rate's benchmark. Grading programs against national averages would be representative of that moving benchmark and provide greater ability to smooth out fluctuations in the organ offer acceptance ratio.

Quality Domain

We also suggest that CMS consider using other measures besides graft survival when evaluating long-term outcomes of transplant patients as described in *Section III.C.5.e. Quality Domain*. A 2022 study found that quantifying meaningful differences in the competency of kidney transplant programs based on 1-year graft survival rates is challenging because of relatively few allograft failure events per program and increasing homogeneity in program performance. Compared with the traditional end point of graft status (allograft failure at 1-year post-transplant), a composite end point that incorporates a measure of allograft function (the recipients' eGFR <30 ml/min per 1.73 m² or graft failure at 1 year) performed better in differentiating between transplant programs with respect to long-term deceased donor graft outcomes. Incorporating granular measures of allograft function into performance metrics instead of using a binary (functioning/failed) indicator can improve patient care by prioritizing allograft function as a measure of program quality¹. Estimated glomerular filtration rate (eGFR) more accurately represents long-term patient outcomes.

¹ Wang, Kaicheng; Deng, Yanhong; Stewart, Darren; Formica, Richard N. Jr.. A Composite End Point of Graft Status and eGFR at 1 Year to Improve the Scientific Registry of Transplant Recipients' Five-Tier Rating System. *JASN* 33(8):p 1613-1624, August 2022. | DOI: 10.1681/ASN.2022010078

Transparency Requirements

The OPTN supports the model's efforts to increase transparency as described in *Section III.8.a. Transparency Requirements*. Increasing transparency throughout the entire organ donation and transplant system, including with patients, is critical. However, it is important CMS ensures information about organ offer acceptance is presented in a way that safeguards patients. Careful consideration is needed regarding how to display information about declined organs to prevent negatively impacting patients and their families. Public disclosure of listing practices should also be carefully evaluated to ensure the information is useful without being burdensome to providers.

Accommodating the proposed transparency requirements will require the development of new reporting measures and data collection systems, which will take significant time and funding to create before the proposed model is implemented. We ask CMS to ensure model participants are fully equipped to successfully implement these requirements. We also request CMS to thoroughly evaluate the administrative and financial burden that the additional data collection and reporting requirements outlined in *Section III.8.a. Transparency Requirements* and the patient-reported outcome measures outlined in *Section III.D.1. Patient-Reported Outcome Performance Measures (PRO-PM)* will have on mandated participants.

Additionally, we encourage CMS to clarify the timing and notification processes for participating centers. CMS should develop charts or other tools that track and communicate performance to participants in real-time. Such performance-related information should be made available to providers in addition to centers so they can better identify areas for improvement and change behaviors as necessary before each performance year ends.

Financial Incentives and Penalties

The OPTN supports the IOTA model goals to increase organ transplants and wants the model to be successful. Therefore, we recommend CMS re-evaluate the proposed incentives and penalties outlined in *Section III.C.5. Performance Assessment* to be significant enough to influence participant behavior. To support participation, the incentives should at a minimum cover the additional administrative costs resulting from the model's requirements.

Alignment of Metrics

The Executive Committee is concerned that misalignment of OPO and transplant program performance metrics could undermine the success of the IOTA model.

Conclusion

Overall, the OPTN supports the goals of this model and believes it aligns with other donation and transplant community initiatives to decrease organ non-use and improve organ offer acceptance rates. We hope to work together to ensure OPTN and CMS initiatives align for the benefit of patients, donors, and their families. We appreciate your consideration of our recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Formica", written in a cursive style.

Richard Formica, MD
President, OPTN Board Directors