UnityPoint Health

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July 16, 2024

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–5535-P
P.O. Box 8013
Baltimore, MD 21244–8013

RE: CMS–5535-P - Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model; published at Vol. 89, No. 97 Federal Register 43518-43634 on May 17, 2024.

Submitted electronically via http://www.regulations.gov

Dear Administrator Brooks-LaSure,

UnityPoint Health appreciates this opportunity to provide comments on this proposed rule related to Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates. UnityPoint Health is one of the nation's most integrated health care systems. Through more than 29,000 employees and our relationships with 375+ physician clinics, 36 hospitals in urban and rural communities, 5 IRFs, and 13 home health agencies across our 8 regions, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin.

For more than 30 years, UnityPoint Health – Iowa Methodist Transplant Center has performed more than 1,000 kidney transplants. One-third of our transplant patients are over the age of 65, and we perform transplants for patients with a body mass index (BMI) over 40. In Iowa, Iowa Methodist Transplant Center has been a leader in the field and was the first:

- To perform robotic-assisted laparoscopic living donor nephrectomy,
- To be an in-center paired exchange,
- To perform a national paired exchange,
- To utilize a humanitarian living donor.

UnityPoint Health appreciates the time and effort of CMS in developing this proposed rule. The UnityPoint Health – Iowa Methodist Transplant Center transplant physician team and administrative team, including system finance, have reviewed this proposal and respectfully offer the following comments.

INCREASING ORGAN TRANSPLANT ACCESS MODEL (IOTA MODEL)

CMS proposes a mandatory six-year model that would test whether performance-based incentive payments paid to or owed by participating kidney transplant hospitals increase access to kidney

transplants for patients with end-stage renal disease (ESRD) while preserving or enhancing the quality of care and reducing Medicare expenditures. The model's proposed standard provisions relate to beneficiary protections; cooperation in model evaluation and monitoring; audits and records retention; rights in data and intellectual property; monitoring and compliance; remedial action; model termination by CMS; limitations on review; miscellaneous provisions on bankruptcy and other notifications; and the reconsideration review process. This proposed rule would apply to Innovation Center models whose first performance period begins on or after January 1, 2025.

Comment: Generally, UnityPoint Health is concerned about the IOTA Model's focus on quantity over quality as well as the additional administrative burdens imposed on transplant centers. As proposed, we urge CMS to revisit the following:

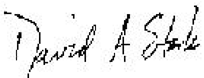
1. Quantity versus quality: Sixty percent of the IOTA hospital participants' final performance score is based on the achievement domain. This domain prioritizes the number of transplants performed over patient quality and outcomes. This emphasis appears at odds with the IOTA Model goal to "improve quality of care before, during and after transplantation" and may lead to transplants for which patients are less likely to do well in the long term. We recommend that this domain be reweighted.
2. Quality score includes misaligned measure: Twenty percent of the IOTA hospital participants' final performance score is based on the quality domain. This domain includes three consensus-based entity (CBE) quality measures, including colorectal cancer screening performed post-transplant. The Colorectal Cancer Screening (COL) (CBE ID: 0034) measure is unrelated to transplant outcomes, shifts primary care responsibilities to transplant centers, and should be removed from the IOTA Model.
3. Access to kidney transplants: Kidney transplants must continue to rely upon science, and we agree that access disparities is an area for improvement. First, we appreciate that CMS declined to implement duplicative social determinants of health (SDOH) reporting/screening requirements. Specifically, we applaud CMS for not requiring (1) collection of demographic data already collected by organ procurement organization (OPOs) and the Scientific Registry of Transplant Recipients (SRTR) or (2) Health Related Social Needs (HRSN) screening which gathers information largely captured by current psychosocial evaluations for waitlisted patients. Duplicative reporting is a waste of resources and a patient dissatisfier. From a care coordination perspective, SDOH information should be collected and maintained by primary care providers/settings, not transplant centers, to assure more holistic services and transitions of care. Second, in terms of health equity, we request that CMS reconsider the health equity performance adjustment in the achievement domain as well as mandating annual standardized health equity plans. We are concerned that the health equity adjustment may simply incentivize shifting of kidney transplants from one type of patient to another and has been proposed without clear evidence supporting its impact on transplant outcomes. The requirements for separate health equity plans adds another administrative burden.
4. Waitlist notifications: The IOTA Model requires monthly notice to waitlisted Medicare patients of organ declines and reason(s) why the organ was declined. This notice is burdensome and costly, it substitutes regulatory guidance over clinical judgment in relation to patient outreach, and it

may ultimately encourage IOTA hospital participants to accept lower-quality kidneys. We request that this notice be eliminated.

Although the IOTA Model is well-intentioned, we believe the over-arching emphasis of quantity over quality will lead to decreased kidney longevity and increased financial costs for transplant centers. As proposed, UnityPoint Health predicts that the IOTA Model may increase the number of transplants, but at the cost of decreased quality and increased financial burden on transplant centers. **Due to these concerns, we recommend that CMS either make this model voluntary or, if mandatory, delay the IOTA Model for at least one year to seek further stakeholder comment and incorporate input.**

We are pleased to provide input on this proposed rule and its impact on our transplant center and patients. To discuss our comments or for additional information on any of the addressed topics, please contact David Stark, Government & External Affairs at David.Stark@unitypoint.org or 515-205-6600.

Sincerely,



David A. Stark, FACHE
Chief of Government Affairs & Philanthropy