Trinity Health

July 15, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-5535-P; Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model

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

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule on the Increasing Organ Transplant Access (IOTA) Model. Trinity Health's comments reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high-quality care for all.

Trinity Health is one of the largest not-for-profit, faith-based health care systems in the nation. It is a family of 121,000 colleagues and nearly 36,500 physicians and clinicians caring for diverse communities across 27 states. Nationally recognized for care and experience, the Trinity Health system includes 101 hospitals, 126 continuing care locations, the second largest PACE provider in the country, 136 urgent care locations and many other health and well-being services. In fiscal year 2023, the Livonia, Michigan-based health system invested $1.5 billion in its communities in the form of charity care and other community benefit programs.

A national leader in payment and care delivery models, Trinity Health advances our Mission through moving payments into alternative payment models with greater accountability for cost of care and clinical outcomes. Trinity Health has 17 Clinically Integrated Networks (CINs) that are accountable for 2 million lives across the country through alternative payment models. Our health care system participates in 14 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes eleven markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. All of these markets participated in the "enhanced track", which qualifies as an advanced alternative payment model (AAPM). Two of the 14 markets also participate in CPC+. In addition, we have participated since 2014 in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative and the Comprehensive Care for Joint Replacement (CJR) program across 37 hospitals. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

Trinity Health has two kidney transplant programs across the health system. Loyola Medicine's kidney transplant program in Illinois performed 260 transplants in 2023. The Trinity Health Grand Rapids kidney transplant program in Michigan performs an average of 100 transplants per year.

Trinity Health supports with the goals of the IOTA model to increase the number of kidney transplants furnished to end-stage renal disease (ESRD) patients; encourage investments in value-based care and quality improvement activities; encourage better use of the current supply of deceased donor organs; address medical and non-medical needs of patients; and increase awareness, education, and support for living donations. Trinity Health urges CMS to address the following issues to fully achieve the model's goals:

- Provide participants with at least a one-year notice before the model launch.
- Begin the model as a voluntary program and shift to a mandatory model after an initial trial period of three years.
- Provide all participants with infrastructure payments to address upfront costs.
- Remove the organ offer acceptance rate measure in the efficiency domain.
- Adopt the payment model from the Kidney Care Choices (KCC) model.
- Remove the requirement to notify patients on the waitlist monthly of the number of times an organ was declined on each patient's behalf.

Model Performance Period

CMS is proposing a six-year model performance period beginning on January 1, 2025, and plans to notify participants of their selection to participate at least three months in advance. Participants will need to invest a significant number of resources to be successful in the model; therefore, three months is not enough time to prepare for the model to launch, including hiring additional colleagues. CMS must provide participants with sufficient time from when policies are finalized until the model launch. Trinity Health urges CMS to finalize policies and provide additional guidance, including participant selection and available waivers, at least one year before the model launch.

Mandatory Participation

Trinity Health is concerned with the mandatory nature of the model. CMS should initially offer an incentive-based voluntary model for programs that are immediately prepared to take on the additional challenges and risks. We would support shifting to a mandatory model after evaluation of an initial trial period of three years.

Participant Selection

Kidney transplant programs that close or suspend operations after the initial IOTA baseline years (2021, 2022, 2023) would likely create a shift of the waitlist population and subsequent transplant volumes to nearby transplant programs. These receiving transplant programs would potentially experience an increase in the number of transplants with little additional effort outside of increased staffing and resources to accommodate this growth in volume. Program suspensions—and especially closures—would likely create displacement of the experienced transplant professionals that could be available for hire at these nearby transplant programs that are accepting the displaced patients, thereby benefiting that program, and easing the increased burden. This volume increase may qualify that program for upside payments from the IOTA program without actual increases in overall transplant volumes in the local, regional, and national (and even with some decreases in overall transplant volumes).

These scenarios are a real concern, as shown by the very recent suspension of the kidney and liver transplant programs at Memorial Hermann Texas Medical Center in Houston, Texas, and the closure of the kidney and liver transplant programs at Milton S. Hershey Medical Center at Penn State Health in Pennsylvania.

The impact of newly initiated kidney transplant programs has the strong potential to have the oppositive effect by absorbing both the patient population and available organs for transplant that might otherwise be attributed to existing nearby transplant centers. The existing transplant center would likely experience a reduction in IOTA points available for their Performance Score, thereby reducing their upside payment, or increasing a downside payback. Even if the total number of transplants performed between the new and existing transplant center(s) is more than the baseline years, the existing programs would be at greater risk of lower performance points, while the new program would not have adequate baseline years for them to qualify for participation in the IOTA Model.

Performance Assessment

Achievement Domain

CMS is proposing the calculation of the transplant target to be based on the best performance in deceased-donor renal transplant and living-related renal transplant in baseline years 2021-2023 plus the national growth rate (7%). Trinity Health is concerned that if a program is growing, then this calculation would produce an unreasonable growth rate. For programs that are pushing beyond the expected growth rate (>100%), the additional 15 points (to 30) may be offset by lower graft survival as centers will be taking more challenges to transplant at a faster rate. Using absolute cutoffs rather than a graduated scale (30-60 instead of 30,45,60 points) would better reward centers trying to achieve the goal of increasing transplants that could offset lower graft survival expected by pushing the limits in donor organ selection. For the calculation of points, Trinity Health believes more reasonable and obtainable goals are needed, for example, 15%, 25%, 35% to gain 30, 45 and 60 points.

Health Equity Performance Adjustment

CMS proposes to apply a health equity performance adjustment, a 1.2 multiplier, to each kidney transplant furnished by an IOTA participant to a patient. Trinity Health encourages CMS to increase the multiplier to 1.25. We also urge CMS to revise the current definition of “low-income patient.” Trinity Health has dialysis patients that get assistance, for example in Illinois, to enroll in commercial plans. These individuals should be considered low income because they often have socioeconomic barriers.

We appreciate that CMS also considered the inclusion of “rural residents”. Trinity Health encourages reconsideration of this factor, in addition to the “low-income population” multiplier, as recipients living in rural areas, regardless of income, have additional challenges in seeking transplant and other personal health care needs. Using the same multiplier as the “low-income” would offer the opportunity to address some of these challenges. If a recipient meets both the low-income and the rural residence, both multipliers should be allowed, as these factors together compound the obstacles faced by this population. A distance calculation (miles from the patient’s home to the transplant center) could also be considered, as transportation and social support solutions differ greatly for those that may live hundreds of miles away from the nearest transplant center.

Efficiency Domain

CMS proposes including the Organ Procurement and Transplantation Network (OPTN's) organ offer acceptance rate measure in the efficiency domain. The organ offer acceptance rate ratio measure is a ratio of observed organ offer acceptances versus expected organ offer acceptances. Trinity Health agrees with CMS’ goal to incentivize kidney organ offer acceptance, optimize the use of available organs, and reduce underutilization and discards of quality donor organs. However, we are concerned that the unintended consequences of this policy may disproportionately affect the socioeconomic group it is meant to serve by encouraging the increased use of marginal kidneys. Utilizing marginal kidneys increases the need for dialysis post-transplant and increased post-transplant surveillance, which is not captured in any current fee for service model, thus the transplant center will

bear the cost of hiring additional staff required for monitoring. Readmission rates could also be higher due to increased use of marginal kidneys.

Trinity Health also has concerns regarding kidney quality for programs that only do kidney transplants. These programs will be compared to centers that do dual organ transplants which generally get the first pick of kidneys if taking multiple organs.

Organ acceptance as a metric also does not account for factors including transportation access which lead to prolonged ischemia times.

We urge CMS to not include the organ offer acceptance rate measure in the efficiency domain. Should CMS finalize the efficiency domain as proposed, to increase acceptance of marginal kidneys we will need to consider preservation options such as normothermic regional perfusion and pump perfusion, which will increase organ acquisition costs. It will be important to consider the increased cost for centers using this technology to increase organ acceptance.

Quality Domain

CMS proposes using an unadjusted rolling "composite graft survival rate," defined as the total number of functioning grafts relative to the total number of adult kidney transplants performed, to assess post-transplant outcomes. This proposed metric works against the goal of IOTA to attempt to transplant more grafts in a more complex patient population without adjustment for allograft and recipient factors. The metric requires both adjustment for donor and recipient risk factors. Trinity Health recommends CMS use the current Scientific Registry of Transplant Recipients (SRTR) metrics.

CMS proposes the following three measures for inclusion in the IOTA Model quality measure set: (1)CollaboRATE Shared Decision-MakingScore (2) Colorectal Cancer Screening 3) the 3-Item Care Transition Measure. This analytic process biases transplant centers that retain patients over those that repatriate patients to referring physicians. It favors high density populations over rural areas where standard nephrologists and primary physicians are more likely to direct non transplant related care. Centers that repatriate patients are not necessarily involved directly in many patient decisions. These are also additional measures that will take up additional coordinator time to complete.

Payment

CMS proposes an alternative payment model (APM) structure that incorporates both upside and downside risk to existing Medicare fee-for-service (FFS) payments for kidney transplants. Trinity Health is concerned that the proposed gain will not cover the cost of the infrastructure build, additional assessment, overhead and personnel. Trinity Health urges CMS to provide all participants with infrastructure payments to address the upfront costs.

The goals for top performance are great for small programs (50%) but we believe are biased against larger programs where it will be difficult to grow by 150%. The goals will be hard to meet with competition in the market and are not sustainable over six years. We are also concerned with the language around unadjusted vs. adjusted outcomes. As a program takes higher risk, it will lose more kidneys.

Trinity Health is no longer participating in the Kidney Care Choices (KCC) model, but from our experience, the first year was always unproductive. We are concerned with the risk timeline in the IOTA model. At minimum, the first two years of the mandatory model should be risk free (no downside) for all participants. The KCC Model includes a payment incentive called the Kidney Transplant Bonus (KTB). KCC participants are eligible for up to $15,000 for every aligned beneficiary with CKD or ESRD who receives a kidney transplant, whether from a living or deceased donor, provided the transplant remains successful. Payment to KCC is considered a reimbursement in the renal replacement therapy (RRT)/ transplant differential. The payment is divided over three years, and the outcome measure looks at if the patient is alive and off RRT. Trinity Health believes this structure makes more sense and urges CMS to adopt it for the IOTA model.

Trinity Health encourages CMS to reconsider inclusion of Medicare Advantage (MA) patients as part of the model performance-based payments. There has been a large increase in the number of Medicare eligible patients going into Medicare Advantage plans. At our Grand Rapids program, the overall Medicare patient population is just over 50% of our total patient population and Medicare Advantage is approaching 70% of our Medicare patient population in 2024. This is not being accounted for in the incentive payments, thus lowering the upside. The potential revenue it would generate would be much less without inclusion of MA patients.

Transparency Requirements

CMS proposes that IOTA participants would be required to inform patients on the waitlist, on a monthly basis, of the number of times an organ was declined on each patient's behalf and the reason(s) why each organ was declined. Trinity Health opposes this requirement, as it would be unnecessary and operationally complex. At the Trinity Health Grand Rapids program, there are nearly 300 patients on the waitlist for a kidney transplant. In a brief review of the Organ Offers Report from the OPTN for the month of May 2024, 134 of the waitlisted candidates received organ offers from 125 distinct deceased donors, for a total of 3,229 match run offers. Of those 3,229, 3,109 were declined, 115 were considered but the organs were not made available to those candidates (either placed with another transplant center, or not offered at all), and five organs were accepted and transplanted for one of our candidates. The logistical complexities required to abstract this offer information and compile a report for every offer received and declined for each individual candidate monthly would be an incredibly burdensome use of resources and require additional staff. Trinity Health does not believe it would increase the number of transplants—and may actually decrease transplant volume due to resources—and would ultimately not improve outcomes.

The reason for organ decline is a complex medical and surgical decision made by experienced transplant medical professionals on a case-by-case basis, guided by evidence-based medicine and years of experience to ensure patients receive a kidney that is determined to be viable, functioning and transplantable. It would be a disservice to the patient to give the false sense that they would have the option of accepting a kidney that the transplant nephrologist and transplant surgeon have deemed unacceptable for transplant. Patients receive education about the different types of deceased donors during their evaluation process and can discuss further throughout their time before transplant.

Health Equity Data Reporting

Trinity Health agrees with CMS' decision not to propose the collection of demographic data as this data is already collected, thereby making such a requirement for purposes of this model potentially duplicative and unnecessarily burdensome.

CMS seeks comment on whether it should include a requirement for IOTA participants to conduct health-related social needs (HRSN) screening and report HRSN data in a form and manner specified by CMS. Trinity Health supports HRSN screening but recommends that CMS streamline reporting requirements. Beginning in 2024, CMS requires all hospitals to report on all five HRSN domains (housing, food, transportation, utilities, interpersonal violence) as part of the Hospital Inpatient Quality Reporting (IQR) program. Instead, CMS should align the IOTA requirements with the IQR and use the IQR data to obtain this information from participants.

Health Equity Plan

All licensed hospitals are currently required by the Joint Commission and by CMS to submit a health equity plan that focuses on the larger systemic issues that the hospitals and communities need to work on. CMS should not require a separate, standalone health equity plan for IOTA and should accept—without review—the health equity plans that are already required.

Attributed Patient Engagement Incentives

Trinity Health agrees with CMS' goal to support attributed patients in overcoming challenges associated with remaining active on the kidney transplant waitlist and adhering to comprehensive post-transplant care coordination. Offering additional incentives (ex. Communication devices, transportation, mental health services, in-home care) will be an immense undertaking. Our programs will need more coordinators, social workers, and support services to refer patients. Transportation, for example, is a challenge that is not entirely up to our programs to solve. Patients at our Grand Rapids program come from the entire west side of Michigan including the Upper Peninsula. Even patients in immediate counties do not always have reliable public transportation. This will require significant planning and additional upfront resources.

Trinity Health appreciates CMS' efforts to increase kidney transplants for ESRD patients. If you have any questions about our comments, please contact me at jennifer.nading@trinity-health.org.

Sincerely,

/s/

Jennifer Nading
Director, Medicare and Medicaid Policy and Regulatory Affairs
Trinity Health