Trinity Health

February 9, 2026

Dr. Mehmet Oz, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-5544-P; Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model

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

Dear Administrator Oz,

Trinity Health appreciates the opportunity to comment on policies set forth in CMS-5544-P. Our comments and recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 127,000 colleagues and more than 29,000 physicians and clinicians caring for diverse communities across 25 states. Nationally recognized for care and experience, the Trinity Health system includes 92 hospitals, 101continuing care locations, the second largest PACE program in the country (a total cost of care program), 121 urgent care locations and many other health and well-being services. Trinity Health has 15 medical groups with 8,200 medical group physicians and providers. Based in Livonia, Michigan, its annual operating revenue is $25.4 billion with $1.4 billion returned to its communities in the form of charity care and other community benefit programs.

Trinity Health has 12 Clinically Integrated Networks (CINs) that are accountable for 2 million lives across the country through alternative payment models. Our health care system participates in 12 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes 10 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 12 markets also participate in the Comprehensive Primary Care Plus Model. In addition, we participated for many years 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.

The Trinity Health Grand Rapids kidney transplant program in Michigan performs an average of 100 transplants per year and has been selected as a participant in the Increasing Organ Transplant Access (IOTA) Model. We support 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 has the following feedback on the proposed rule with more detail in the comments below:

- Trinity Health supports finalizing the proposed low-volume threshold.
- Prior to finalizing the risk adjustment methodology, CMS should provide more detail and offer a comment process for stakeholder feedback. In addition, any risk adjustment should be prorated from the time of transplant and CMS should adjust the proposed transplant and donor recipient characteristics to ensure they are appropriate for the model.
- When considering the scoring methodology for the composite graft survival rate, we strongly recommend CMS maintain the current point distribution and ensure that participants won't be penalized for growth
- Should CMS choose to decrease the maximum upside risk payment from $15,000 to $10,000 per Medicare kidney transplant, the agency must also adjust the downside payments proportionally to fairly balance lowering the maximum upside payment.
- Trinity Health supports revising the EUC policy for the IOTA Model as proposed.
- CMS should not finalize the proposed requirement to notify IOTA waitlist beneficiaries of the number of times an organ is declined on their behalf, as this data point could provide misleading information, would not increase the number of transplants or improve outcomes, and would create administrative burden for participants.
- Trinity Health supports the provisions to require IOTA participants to notify their eligible waitlist patients when their waitlist status has changed from active to inactive and provide notice to attributed patients via electronic methods.

<u>Low-volume Threshold</u>
CMS previously finalized a low-volume threshold requiring a kidney transplant hospital to have performed 11 or more kidney transplants for patients 18 or older annually in each of the three baseline years in order to be eligible for selection into the IOTA Model. The proposed rule would raise the low-volume threshold from 11 to 15.

Trinity Health supports increasing the low-volume threshold.

<u>Composite Graft Survival Rate</u>
CMS proposes to adopt a risk adjustment methodology to account for several transplant recipient and donor characteristics and would develop a risk score for each IOTA transplant patient based on these variables and then calculate normalized and adjusted composite graft survival rates to control for differences in kidney transplant outcomes. In addition, the rule would update the scoring approach for the quality domain. The agency would continue its previously finalized policy that awards points based on quintiles of performance relative to national ranking but proposes a different point distribution.

Participants need more information on the proposed risk-adjustment methodology. **Prior to finalizing this policy, we urge CMS to provide the detailed methodology and seek comments from stakeholders.** As part of this detail, CMS should clarify from where they will obtain measure information—Trinity Health recommends CMS use the established data from the current Scientific Registry of Transplant Recipients (SRTR) metrics.

Further, the risk adjustment methodology must be tested and verified to ensure that it's appropriate for this model and the finalized risk adjustment policy should be prorated from the time of transplant.

In addition, some of the proposed characteristics need to be revised to ensure appropriateness for the model, including:
- *Hypertension with or without cardio disease* is not reported to the OPTN and therefore should be removed.

- *PRA* – The incorrect PRA is referenced in the proposed rule. PRA associated with transplant is Percent Reactive Antibodies and not plasma renin activity. In addition, PRA would not be an appropriate characteristic for donors and we urge CMS to remove the characteristic from that group.

We recommend that CMS *add* the following characteristics to the risk adjustment methodology:

- *Length of time since transplant* – a patient transplanted at the very beginning of the IOTA model has a much higher risk than a patient transplanted toward the end of a program and this should be considered in the risk adjustment methodology.
- *Age* – we recommend a sliding scale since every year of age will increase risk factors.
- *Amount of cold ischemic time and warm ischemic time to donor characteristics*.

When considering the scoring methodology for the composite graft survival rate, we strongly recommend CMS maintain the current point distribution and ensure that participants won't be penalized for growth (which they have little control over). For example, a neighboring hospital that is located 1 mile away from an IOTA Model participant is adding an adult kidney transplant program and will start transplants this summer. This will likely impact the patient population for IOTA participants near this new program as well as available organs since they'll be competing for the same organs.

Alternative Payment Design

CMS seeks comment on whether Medicare Advantage patients should be included in the calculation of risk-based payments and noted the agency could choose to decrease the maximum upside risk payment from $15,000 to $10,000 per Medicare kidney transplant. CMS projects that these changes to the model would approximately offset each other and have a net zero impact on model savings.

If this proposal is finalized, we urge CMS to also adjust the downside payments proportionally to fairly balance lowering the maximum upside payment.

Extreme and Uncontrollable Circumstances

The model currently uses determinations made under the Quality Payment Program (QPP) with respect to whether an extreme and uncontrollable circumstance (EUC) has occurred and the affected. The proposed rule would modify the EUC policy such that the agency may, at its sole discretion, apply flexibilities if the participant is located in an emergency area during an emergency period for which the Secretary has issued a waiver under section 1135 of the Social Security Act and if the participant is located in a county, parish or tribal government designated in a major disaster declaration under the Stafford Act.

Trinity Health supports revising the existing EUC policy and agrees that the current policy may not fully account for the broader impacts that an EUC might have on a participant's ability to perform in the IOTA model if organ allocation systems are disrupted or disaster conditions disproportionately affect post-transplant outcomes.

Notification of Declined Organ Offers

CMS proposes that IOTA participants be required to notify eligible IOTA waitlist beneficiaries of the number of times an organ is declined on that beneficiary's behalf at least once every six months that the beneficiary is on the waitlist, as well as note in the beneficiary's medical record that the notification was delivered.

Trinity Health opposes this requirement. The number of times that an organ is declined on a beneficiary's behalf is an inappropriate number to keep track of and could provide misleading information. 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.

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 period from July 2025 to January 2026, 179 of the waitlisted candidates received organ offers from 552 distinct deceased donors, for a total of 11,557 match run offers. Of those, 10,507 were declined, 1,018 were considered but the organs were not made available to those candidates (either placed with another transplant center, or not offered at all), and 32 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 every six months would be an incredibly burdensome use of resources. **Trinity Health does not believe it would increase the number of transplants nor would it improve outcomes. We urge CMS not to finalize this provision.**

Change in Waitlist Status

Transplant hospitals are required to notify patients when they are first added to or removed from a waitlist. The proposed rule would require IOTA participants to also notify their eligible waitlist patients when their waitlist status has changed from active to inactive, as well as the reason for the change in waitlist status and how the patient may become active again (e.g., by updating personal information or providing new clinical data). Participants would have to provide this notification to the beneficiary electronically or by mail within 10 days of the change in waitlist status and annually thereafter.

Trinity Health supports this provision.

Beneficiary Protections

IOTA Model participants are currently required to provide notice to attributed patients that they are participating in the model. CMS proposes that if a patient has opted out of receiving paper communication and chosen to receive communication through electronic methods, this notification can be distributed through that agreed upon electronic method.

Trinity Health supports this provision.

Conclusion

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

Sincerely,

/s/

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