American Kidney Fund®
FIGHTING ON ALL FRONTS

July 16, 2024

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS–5535–P: Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model

Dear Secretary Becerra and Administrator Brooks-LaSure,

The American Kidney Fund (AKF) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Service's (CMS) proposed rule on the Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model.

The American Kidney Fund fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

AKF commends the administration for its continued efforts to improve care for people living with kidney disease and to advance health equity. We support the overall framework of the IOTA model and strongly support its goals: to maximize the use of deceased donor kidneys; identify more living donors and assist them through the donation process; improve care coordination and patient-centeredness in the kidney transplant process; create a more equitable transplant process; address health disparities; and improve quality of care before, during and after transplantation.[1]

[1] https://www.cms.gov/priorities/innovation/innovation-models/iota

We offer the following comments of support and recommended changes to certain provisions of the IOTA model.

AKF is also a member of Kidney Care Partners (KCP), an alliance of members of the kidney care community. In addition to our comments below, we support the comments that KCP has submitted.

Achievement Domain

AKF supports the proposed methodology for the achievement domain and its measurement of IOTA participant performance, which is based on the number of transplants performed on patients 18 years of age or older, regardless of payer, relative to a target and subject to a health equity performance adjustment. We agree with CMS that the IOTA model should test the effectiveness of the model's incentives to change outcomes, specifically the receipt of a kidney transplant. We agree with CMS's rationale to not include in the achievement domain a waitlisting measure, as that would shift the focus towards getting patients on the kidney transplant waitlist, instead of increasing the number of kidney transplants furnished by IOTA participants.

We also strongly support the proposed inclusion of a health equity performance adjustment applied to each transplant furnished to a low-income population IOTA transplant patient, which would be defined as a patient in one or more of the following groups: the uninsured; Medicaid beneficiaries; Medicare-Medicaid dually-eligible beneficiaries; recipients of the Medicare low-income subsidy (LIS); and recipients of reimbursements from the Living Organ Donation Reimbursement Program administered by the National Living Donor Assistance Center. We believe this is an appropriate incentive to encourage IOTA participants to address barriers that low-income populations face in the transplant process and to help reduce disparities in access to transplant. The health equity performance adjustment is also an important tool to ensure IOTA participants are not unfairly penalized if they serve a high number of low-income populations.

While we support the proposed methodology for the achievement domain, we recommend that CMS consider making adjustments to the proposed performance achievement targets to ensure they are realistically achievable for IOTA participants. Setting realistic achievement targets is critical to drive meaningful changes from IOTA participants that lead to increased access to kidney transplants for patients. Setting unattainable achievement targets at the outset will hinder the IOTA model's ability to accomplish its goals. We encourage CMS to engage with stakeholders to develop achievement targets that will set up the model for greater success.

Efficiency Domain

AKF supports the proposal to include the organ offer acceptance rate ratio in the efficiency domain. We believe this is an appropriate measure to encourage IOTA participants to increase the utilization of available organs, improve efficiency in the organ offer process and improve acceptance practices for offers received. As CMS notes, the kidney discard rate has risen and

continues to trend upward despite the introduction of a new allocation system in 2021. We believe that including the organ offer acceptance rate ratio in the efficiency domain is the most promising approach to reduce discards of quality donor organs in the IOTA model.

We concur with CMS's reasoning in the proposed rule to not include various waitlist metrics in the efficiency domain. Focusing on waitlist management metrics such as various time to transplant measures would distract from increasing the rates of transplant and reducing the kidney discard rate. The use of waitlist metrics in the IOTA model could exacerbate inequities by discouraging IOTA participants from listing patients most in need of a transplant and who struggle with barriers to transplant.

Quality Domain

AKF appreciates CMS's proposed approach to a quality measure set that would assess an IOTA participant's performance on aspects of care that are holistic and patient-centered. As a general principle, AKF believes quality measurement programs should include a streamlined set of meaningful measures that drive improvements in clinical outcomes and patient experience while minimizing administrative burden on health facility staff. We recommend that CMS continue to engage with stakeholders to determine what may be the most appropriate quality measure set for the IOTA model.

We have concerns that the CollaboRATE Shared Decision-Making Score and the 3-Item Care Transition Measure, which CMS proposes to include in the measure set, lack evidence for their usefulness in kidney transplant candidates or people living with chronic kidney disease (CKD) or end-stage renal disease (ESRD). CMS also notes that they considered inclusion of the Patient Activation Measure (PAM) because of its potential to encourage IOTA participants and their waitlisted patients to work together to maintain the patient's active waitlist status. CMS notes that they were unable to find literature to support this hypothesis, so the PAM is not included in the proposed measure set. However, we recommend that CMS reevaluate possible inclusion of the PAM in the IOTA model measure set after the public release of data on the PAM's use in the voluntary Kidney Care Choices (KCC) model, which is expected soon.

Performance-Based Payments

AKF supports the use of performance-based upside risk payments and downside risk payments to achieve the goals of the IOTA model. However, we are concerned that the amount of upside and downside risk payments that CMS proposes may not be enough to incentivize IOTA participants to make significant changes to their processes that lead to increased kidney transplants and improvements in patient care and patient experience. We recommend that CMS consider increasing the upside and downside risk payments to better incentivize IOTA participants to take steps to increase access to kidney transplants, while disincentivizing them from maintaining the status quo. We also recommend that CMS consider making a corresponding increase to the health equity performance adjustment.

Medicare Advantage

CMS considered including transplants furnished to attributed patients enrolled in Medicare Advantage (MA) in the model performance-based payments, but decided not to include them in the proposed rule. We recommend that CMS reconsider this decision and further investigate pursuing a waiver of section 1851(i)(2) of the Social Security Act to include attributed patients enrolled in MA in the calculation of the performance-based payments.

As CMS is aware, the share of Medicare ESRD beneficiaries enrolled in MA has increased significantly since 2021, the first year all ESRD beneficiaries were allowed to enroll in MA. In December 2020 the share of ESRD beneficiaries enrolled in MA was 27 percent; by December 2022 it was 47 percent.[2] Given the growing enrollment in MA among ESRD beneficiaries and Medicare beneficiaries generally, it is imperative that CMS Innovation Center payment models better reflect this changing Medicare landscape. The IOTA model incentives would have a greater effect on the model's goals and the ability of IOTA participants to take the necessary steps to increase access to transplant and improve patient care if attributed patients enrolled in MA were included in the performance-based payments.

Transparency into Kidney Transplant Organ Offers

AKF supports CMS's proposal to add requirements to increase transparency for IOTA waitlist patients who are Medicare beneficiaries, which would require an IOTA participant to inform the Medicare beneficiary, on a monthly basis, of the number of times an organ is declined on their behalf and the reason(s) for the decline. We also support the proposal to require IOTA participants to review transplant acceptance criteria and organ offer filters with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist. We have heard from many patients about their frustration with the lack of communication and transparency they have encountered with regards to kidneys that have been declined on their behalf. These proposed requirements in the IOTA model are important steps to offer opportunities for shared decision-making between IOTA waitlist patients and IOTA participants, and to improve the quality of care and the patient experience.

While we recognize CMS's intent to provide flexibility to IOTA participants by not prescribing the method of notification in which they must inform a waitlist patient about transplant organ offers declined on their behalf, we recommend that at least once a quarter, the method of notification should be by phone/video call or during an in-person visit. If a goal of this transparency requirement is to foster shared decision-making, a verbal conversation where questions and answers can be exchanged in real time is more conducive to that than just sending an email, letter, or portal message.

[2] https://www.medpac.gov/wp-content/uploads/2023/03/Dialysis-Dec-2023-SEC.pdf

Health Equity Plan

AKF supports the proposal that would require IOTA participants to submit a health equity plan for performance year (PY) 2 through PY 6. We believe that this requirement aligns with other CMS Innovation Center models and would promote health equity across the transplant process. Given the longstanding health disparities in kidney care and transplantation, it is imperative that IOTA participants provide a meaningful plan that identifies the disparities in the populations they serve and the initiatives they plan to implement to address those disparities. In combination with the health equity plan, it is important for CMS to assess an IOTA participant's progress on implementing its health equity plan, and to work with the IOTA participant to correct any identified problems.

Part B and Part D Immunosuppressive Drug Cost Sharing Support

AKF strongly supports the proposal to allow IOTA participants to subsidize, in whole or in part, the cost sharing associated with immunosuppressive drugs covered by Part B, the Part B-ID benefit, and Part D for attributed patients that receive immunosuppressives through those programs but who do not have secondary insurance that could provide cost sharing support. We also support the safeguards proposed by CMS for the Part B and Part D immunosuppressive drug cost sharing support policy.

Being able to afford their immunosuppressive drugs is a consistent concern we hear from patients. This is especially true for Medicare ESRD fee-for-service (FFS) beneficiaries under the age of 65 and who live in a state where they cannot access a Medigap supplemental plan that can help cover the 20 percent cost sharing for their immunosuppressive drugs. Allowing IOTA participants to subsidize the cost sharing for immunosuppressive drugs for eligible attributed patients is an important tool to ensure all patients can access the immunosuppressives they need, adhere to their drug regimen, and maintain the health of their transplanted kidney.

Attributed Patient Engagement Incentives

AKF supports the proposal to allow IOTA participants to offer the following attributed patient engagement incentives under certain circumstances: communication devices and related communication services that directly pertain to communications between IOTA participants or IOTA collaborators and attributed patients; transportation to and from a transplant hospital that is an IOTA participant and between other providers involved in the provision of ESRD care; mental health services to address an attributed patient's behavioral health need pre- and post-transplant; and in-home care to support the health of the attributed patient or the kidney transplant in the post-transplant period.

We believe these patient engagement incentives and granting IOTA participants the flexibility to provide them under certain circumstances and under the restrictions and safeguards outlined in

the proposed rule are an appropriate way to help address the barriers that patients may face in remaining active on the kidney transplant waitlist and adhering to their post-transplant care plan.

Thank you for the opportunity to provide comments on this proposed rule.

Sincerely,

LaVarne A. Burton
President and CEO