KIDNEY CARE PARTNERS

August 25, 2023

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

Re: CMS–1782–P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure,

On behalf of the more than 30 organizations working together to advance kidney care through Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments on the "End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model" (Proposed Rule). This letter focuses on the proposals related to the ESRD Quality Incentive Program (QIP) and the ESRD Treatment Choices (ETC) model that are included in the Proposed Rule. KCP submitted comments on the ESRD market basket update and the post-Transitional Drug Add-on Payment Adjustment (TDAPA) add-on adjustment in a letter on July 28, 2023. Our comments on the other proposals in the Proposed Rule and the acute kidney injury reimbursement rate were submitted in a separate letter on August 7, 2023. Our response to the request for information on the low-volume adjuster will be submitted in a separate letter.

Kidney Care Partners is a non-profit, non-partisan coalition of more than 30 organizations comprising patients, physicians, nurses, dialysis professionals, researchers, therapeutic innovators, transplant coordinators, and manufacturers dedicated to working together to improve the quality of care for individuals living with kidney disease.

In sum, KCP supports many quality provisions of the Proposed Rule including:

- The proposal to revise the definition of the minimum total performance score (mTPS).
    - KCP agrees with the use of a proxy median of zero for new reporting measures when there is no data available prior to the first performance period. An analysis conducted by CDRG demonstrates that this approach strikes the correct balance of allowing the measure to be included in the calculation without disadvantaging facilities unfairly.

- The codification of the ESRD QIP measure adoption, retention, and removal policies.
    - KCP continues to support the transparency that these policies create for evaluating measures and appreciates that CMS proposes to codify the current policies.
- The proposed performance standards, eligibility requirements, and payment reduction scale for PY 2026.
    - KCP appreciates CMS's continue reliance on a consistent methodology year-over-year to allow patients and care partners, as well as providers, to be able to compare QIP performance over time in a consistent manner.
    - KCP remains concerned that the eligibility requirements result in smaller facilities being inappropriately penalized, as we have noted in detail in previous comment letters. We encourage CMS to engage actively with KCP to allow the QIP to better support small dialysis facilities.
- The continuation of the current methodology for setting the performance period, performance standards, and scoring for PY 2027.
    - As noted in the bullet above, KCP supports the continuation of the current methodology for future years on the ESRD QIP.
- The proposed revisions to the measure domains and measure weights beginning with the PY 2027 ESRD QIP (with the caveats related to our comments about certain measures).
    - KCP requests that CMS engage actively with KCP to streamline the QIP and the Dialysis Five Star programs so that they are more focused on giving more weight to measures that matter. We support the proposed domains and weights for PY 2026 with the caveat that they be adjusted based on KCP's recommendations on specific measures.

While we continue to support many of the ESRD QIP measures, this letter outlines recommendations to address concerns related to a few of the measures that we request CMS make before finalizing the Proposed Rule. KCP remains concerned that there are too many measures in the ESRD QIP to appropriately incentivize performance and strongly recommends that CMS engage actively with KCP to streamline the QIP and the Dialysis Five Star programs. In addition, we ask that prior to the CY 2025 ESRD PPS rulemaking that the ESRD measures and QIP staff engage with KCP to address growing concerns about the measure set and weighting distributions. For example, there are concerns that the reporting measures weights are disproportionately low relative to the resources required to collect and report the information. We suggest that CMS convene a stakeholder workgroup or technical expert panel to consider alternative approaches to weighting the measures.

KCP also supports the clarifications of the ETC Model policies related to review determinations. We agree with the rationale expressed in the Proposed Rule that the

clarifications will "ensure accountability" and to increase awareness about the availability of administrative review among ETC Participants.[1]

I. KCP Comments on ESRD QIP Measures

KCP appreciates the efforts CMS has made to review and reconsider measures that are part of the ESRD PPS. We reiterate our strong support for the ESRD QIP. As the first Medicare value-based purchasing program, the Medicare ESRD QIP has provided a foundation for the ongoing CMS efforts to expand value-based purchasing successfully within the Medicare program as a whole. Yet, we believe an opportunity to take the program to the next level continues to be missed. Specifically, we encourage CMS to work with KCP prior to the next rulemaking cycle commencing to transform the QIP into a more meaningful program for individuals receiving dialysis by focusing on measures that matter, those that are actionable by dialysis facilities, and those that are scientifically reliable and valid so that the program reflects performance accurately. As we have noted in the past, we reiterate our request that CMS expand its efforts to reduce the measures included in the ESRD QIP and transfer some measures to the Facility Compare Five Star program. Implementing these recommendations would allow the community to address some of the gaps in treatment and care options to improve outcomes and address disparities in health care.

The comments in this letter focus on the specific proposals outlined in the Proposed Rule; however, we continue to encourage CMS to consider the recommendations we have made in previous comment letters specific to our concerns about measures not highlighted in this Proposed Rule and that remain in the ESRD QIP.

A. Measures for PY 2026

1. Facility Commitment to Health Equity Reporting.

KCP believes that a commitment to health equity among ESRD providers is paramount and continues to support the efforts of CMS to address such inequities in healthcare; however, we are concerned that more work needs to be completed before this measure should be included in the ESRD QIP. We first note that a general prerequisite for KCP to support inclusion of a measure in any accountability program is submission to CMS's Consensus Based Entity (CBE) for endorsement for use within both the intended population and care setting. Additionally, we share the MAP's concern that a simple attestation measure such as this one will not effectively drive improvement in health equity, and we fear it will serve as little more than an additional administrative burden; we look forward to Battelle's Partnership for Quality Measurement's (PQM) input on this issue during the measure's upcoming endorsement review. Finally, we note that as currently specified, the measure requires dialysis facilities to attest that

[1] *See* Display Copy 244.

it "inputs demographic and/or SDOH information collected from patients into structured fields, interoperable data elements using a certified EHR technology." We believe this language was imported from the IPPS measure; however, dialysis facilities are not required to use certified EHR technology, and it is doubtful that any currently do. Given that each measure domain is "all or nothing," every dialysis facility would fail Domain 2 by attesting "no" to subpart C. We propose that CMS instead use the following phrase: "Our facility inputs demographic and/or SDOH information collected from patients into structured fields." And as always, KCP invites CMS to work with the renal community to develop more meaningful, actionable performance measures.

2. COVID-19 Vaccination Coverage among HCP Report Measure.

KCP supports this measure for use in the QIP, conditional on review and endorsement by CBE. We appreciate the CDC's recognition of the importance of vaccinations among individuals on dialysis. Dialysis facilities have worked diligently to reduce the spread of COVID-19 through administering vaccines to such individuals and the healthcare professionals working in their facilities. Even so, the community continues to face significant opposition to vaccines in certain areas of the country. KCP thus applauds the efforts of CMS, the CDC, and other federal agencies to improve immunization rates and public understanding about the importance of the vaccines in protecting against morbidity and mortality.

3. Ultrafiltration Rate Reporting Measure.

KCP concurs with CMS's proposal to remove the Ultrafiltration Rate Measure from the ESRD QIP. Given emerging concerns about the potential confounding impact of both patient body size and the frequency of high-UFR treatments on the relationship between higher UFR and increased mortality, we believe the metric may prove overly prescriptive if converted to a clinical measure, limiting providers' ability to effectively apply their best clinical judgement in accordance with the dialysis recipient's current blood volume status on a case-by-case basis. However, we believe the measure has served an important purpose in the QIP by highlighting the value of monitoring UFRs, increasing focus on this critical aspect of dialysis care. We also believe there is value in an ongoing discussion of UFRs for quality improvement within individual facilities, along with other clinical markers of fluid management.

4. Standardized Fistula Rate Clinical Measure.

KCP supports measures focusing on the reduction of catheters and increasing the number of individuals on dialysis with an AV Fistula, when appropriate. As emphasizing the long-term catheter rate in the ESRD QIP would effectively achieve both goals, we thank CMS for taking KCP's previous comments into account and support CMS's proposal to remove the Standardized Fistula Rate measure from the QIP. However, we urge CMS to continue to monitor vascular access types to ensure AVF rates do not begin to fall significantly in favor of AVGs.

5. Clinical Depression Screening and Follow-Up Measure.

While monitoring for clinical depression is important, KCP notes that the Clinical Depression Screening Measure is topped out, with the proportion of individuals on dialysis being screened in 2016, 2017, and 2018 equaling 96.8, 98.6, and 98.8 percent respectively.[2] We believe this measure should be removed from the QIP so that it is more effective at driving improvement in areas where there are greater gaps in care. To provide individuals and their care partners with information about how individual facilities perform in terms of screening for and responding to clinical depression, CMS could include it in the Facility Compare program instead. We further question whether the potential impact of this measure is sufficient to justify the additional burden of its use as a clinical measure in the QIP. In particular, we note that while a positive depression screen is intended to prompt the facility to ensure proper follow-up takes place, HHS recently estimated that nearly 130 million people live in one of the 5,930 federally designated mental health care Health Professional Shortage Areas. Less than one-third of the US population (28%) lives in an area where there are enough psychiatrists and other mental health professionals available to meet the needs of the population, with most states having fewer than 40% of the mental health professionals needed, and more than half (51%) of US counties having no practicing psychiatrists.[3][4] in the absence of appropriate, timely, and affordable resources, we fear the measure will ultimately not have sufficient clinical impact to justify the additional administrative burden and associated lost opportunity costs of direct patient care.

B. Measures for PY 2027: Social Drivers of Health Screening Reporting Measure; Screen Positive Rate for Social Drivers of Health Reporting Measure.

KCP continues to support the efforts of CMS to address inequities in healthcare, but we are concerned with the proposed integration of these two health-related social needs (HRSNs) screening measures into the QIP measure set. As a threshold matter, given the unprecedented nature of these measures and the unknown risks and benefits of their adoption into a penalty-based program such as the QIP, we again note that review by CMS's CBE, which has not yet occurred, is of particular importance. One concern we believe should be addressed in particular would be the administrative burden placed on facilities that could take away from direct patient care time. In particular, we would like an assessment of the administrative burden.

As we described in detail in our July 2021 letter to the Office of Management and Budget (OMB) request for information "Methods and Leading Practices for Advancing Equity

[2] NQF, "NQF Report of 2018 Activities to Congress and the Secretary of the Department of Health and Human Services" 13 (March 1, 2019).
[3] U.S Department of Health and Human Services. Protecting Youth Mental Health. https://www.hhs.gov/sites/default/files/surgeon-general-youth-mental-health-advisory.pdf. Accessed August 21, 2023.
[4] KFF. State Health Facts. Mental Health Care Health Professional Shortage Areas (HPSAs) as of Sept. 30, 2021. San Francisco, CA: KFF. Accessed August 21, 2023

and Support for Underserved Communities Through Government,"[5] patients with kidney disease are disproportionately from socioeconomically disadvantaged communities and experience inequities in the delivery of healthcare. KCP, thus, continues to support CMS's efforts to assess and account for social risk factors[6] in the ESRD QIP and other quality programs through adjusters and other mechanisms, including the use of data and information from quality metrics, to support greater attention to equity and to identify barriers that affect the delivery of kidney care to individuals from underserved communities. However, we again note that the right balance must be struck to ensure that disparities are identified and addressed without inadvertently disincentivizing the provision of care to more medically complex patients or underserved communities. KCP is concerned that the proposed measures do not strike that balance. Even with the limited information provided, we anticipate that use of the measures in a penalty-based program such as the QIP might in fact perpetuate the very disparities CMS is attempting to address.

We concur that the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures would likely provide additional support to facilities and dialysis organizations in ongoing internal quality improvement efforts to identify and address persistent disparities in the ESRD population. However, it is unclear if and how these measures, particularly the Screen Positive metric, would be useful to patients when selecting a facility, as this information is likely more indicative of the socioeconomic vulnerability of the patients a facility serves than of the quality of care it provides. Likewise, penalties for poor performance on the Screen Positive measure would undoubtedly disproportionally and paradoxically impact the most financially vulnerable facilities treating the most socially and medically disadvantaged patients.

Finally, as was highlighted recently in JAMA, individuals' social risks and social needs, though used interchangeably by policymakers and healthcare providers, are often very different—and require different tools and methods. Social *risk* screening relies on validated screening instruments to identify individual-level adverse social factors, while social *needs* screening queries patients about their *own* priorities and perceptions of those needs and their desire for assistance. The former may inadvertently emphasize paternalistic care, whereby clinicians attempt to address *their* interpretation of an individual's needs, with little attention to or respect for each person's *own* interpretation or their decision on whether to seek assistance.[7] As was recently illustrated by implementation studies of widespread HRSN screening in pediatric primary care beginning in 2016, there was significant concern expressed particularly among low-income minoritized families, who conveyed feelings of shame, fears of

[5] Kidney Care Partners. "KCP Letter to OMB on 'Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government Request for Information.'" July 6, 2021. Accessed June 27, 2023.

[6] Borrowing from the Office of the Assistant Secretary for Planning and Evaluation's (ASPE) definition from its 2016 Report to Congress on Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs, "social risk factors" include dual enrollment in Medicare and Medicaid as a marker for low income, residence in a low-income area, Black race, Hispanic ethnicity, and residence in a rural area.

[7] Garg A, LeBlanc A, Raphael JL. Inadequacy of current screening measures for health-related social needs. JAMA. Published online August 21, 2023. doi:10.1001/jama.2023.13948. Accessed August 22, 2023.

being judged and discriminated against by the healthcare team, and frustration with disclosing sensitive needs—often without getting adequate assistance in return. These finding again illustrate the potential for these well-intentioned mandates to paradoxically impede progress in health equity and increase long-standing racial and socioeconomic inequities and mistrust of the healthcare system.[8] We thus reiterate our strong concern that these two social risk measures are wholly inappropriate for use in the QIP, wherein the risk for erosion of patient dignity and autonomy is further heightened by linking screening and outcomes to fear of financial penalties. We urge CMS and policymakers to instead focus resources on developing a means of conducting true, patient-centered, empathetic, and equitable social *needs* screening that relies on the individual's own identified needs and desire for assistance, as well as ensuring the availability of adequate and appropriate social care resources in response to identified needs.

II. Conclusion

Thank you again for the opportunity to provide comments on the Proposed Rule. Please do not hesitate to reach out to our counsel in Washington, Kathy Lester, if you have any questions. She can be reached at klester@lesterhealthlaw.com or 202-534-1773.

Sincerely,

John Butler
Chairman

[8] Schleifer D, Diep A, Grisham K. *It's about trust: Parents' perspectives on pediatricians screening for social needs*. United Hospital Fund. Published June 24, 2019. Accessed August 22, 2023.

Appendix A: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Society of Nephrology
American Society of Pediatric Nephrology
Ardelyx
AstraZeneca
Atlantic Dialysis
Baxter
Cara Therapeutics
Centers for Dialysis Care
Cormedix
CSL Vifor
DaVita
Dialysis Care Center
Dialysis Patient Citizens
DialyzeDirect
Dialysis Vascular Access Coalition
Fresenius Medical Care
Greenfield Health Systems
Kidney Care Council
NATCO
Nephrology Nursing Certification Commission
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Unicycive