



August 17, 2022

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

Re: CMS-1768-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 [ESRD] Prospective Payment System [PPS], Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury [AKI], End-Stage Renal Disease Quality Incentive Program [QIP], and End-Stage Renal Disease Treatment Choices [ETC] Model Proposed Rule”¹ (Proposed Rule). This letter focuses on proposals related to the ESRD QIP and the ETC Model that were not addressed in our August 4th letter. These include:

- The revisions to the measure domains and domain and measure weights beginning with PY 2025;
- The request for information (RFI) on quality indicators for home dialysis patients.
- The potential inclusion of two social drivers of health (SDoH) measures in the ESRD QIP;
- The overarching principles for measuring health care quality disparities across CMS programs;
- The performance payment adjustment achievement scoring methodology in the ESRD Treatment Choices (ETC) model;
- The kidney disease education services under the ETC model; and
- The publication of participant performance in the ETC model.

In our letter dated August 4th, we provided our comments on: (1) the flexibilities for the ESRD QIP in response to the COVID-19 public health emergency (PHE); (2) the technical measure specifications for the Standardized Hospitalization and Standardized Readmission Ratio/Rate measures for PY 2023 and PY 2024; (3) the updates to the

¹87 Fed. Reg. 38464 (June 28, 2022).

performance standards for PY 2023; (4) the COVID-19 Healthcare Personnel (HCP) Vaccination reporting measure, as well as comments related to the existing measure set; (5) the performance standards, eligibility requirements, and payment reduction scale for PY 2025; and (6) the updates for the PY 2026 QIP.

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.

As noted in our first letter, KCP appreciates the ongoing opportunity to work with the Biden-Harris Administration as it seeks to improve access to high-quality kidney care and address inequities in the delivery of health care that those individuals living with kidney disease and kidney failure too often experience. The ESRD QIP value-based purchasing program has helped provide transparency and promoted patient-driven decision-making.

I. ESRD QIP Proposal Comments

A. KCP Remains Concerned that the Proposed Revisions to Measure Domains and to the Domain and Measure Weights used to Calculate the Total Performance Score (TPS) Beginning with the PY 2025 ESRD QIP Do Not Address Ongoing Recommendations to Better Tailor the Domains and Weights to Meaningful Patient Outcomes.

In previous comment letters, KCP has raised concerns about the domains and weighting of measures in the ESRD QIP. While we appreciate the intent behind the proposals in this rulemaking cycle, we do not believe it addresses the underlying problem. Rather than finalize these current proposals, KCP recommends that CMS: (1) reduce the number of measures used in the ESRD QIP as outlined in our August 4th comment letter and (2) work with the KCP and other stakeholders outside of the rulemaking process to allow for a fuller dialogue than is available in the statutorily dictated notice-and-comment rulemaking period before proposed changes to the domains and weights. These steps will promote the Agency's National Quality Strategy and goal of "promot[ing] the highest quality outcomes and safest care for all individuals",² as well as align with the CMS Strategic Pillar to engage partners "throughout the policymaking process."³

As CMS recognizes, too many measures in any value-based purchasing program can be unduly burdensome on providers and dilute the impact of important measures, no matter the weighting scheme, so that patients can no longer distinguish performance. As

²Michelle Schreiber, M.D.; Adam C. Richards, MA; Jean Moody-Williams, RN, MPP; Lee A. Fleisher, M.D. "The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality." <https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality>. (June 6, 2022).

³CMS. "CMS Strategic Pillars." <https://www.cms.gov/cms-strategic-plan>. (Aug. 3, 2022).

we have discussed, CMS should reduce the measures in the ESRD QIP so that when patients and caregivers see the TPS, they can easily understand how the measures are driving the overall performance of the facility. Reducing the measures to those that drive critical aspects of care for which there is a gap in performance will incentivize facilities to devote resources to the measures that matter the most in improving patient outcomes. Because the Congress established the ESRD QIP to create such incentives, it is important that the measures used in the program reflect that intent.

As we have noted in previous letters, KCP believes that the weighting of measures should be aligned to their clinical value and importance to patients. As we reviewed the proposed recommendations for the new weights, our members expressed great concerns about the weighting generally and about the influence that the STrR and ICH CAHPS would have in skewing the TPS. This impact is particularly troubling given the validity issues with both measures. In addition, we believe that CMS should weight the catheter measure greater than the fistulas. In previous letters, we have highlighted the fact that the equal weighting and lack of a graft measure has led to patients having to endure attempts to place AV fistulas when clinically inappropriate. The evidence is overwhelming that AV fistulas and AV grafts are preferable for improved outcomes. Weighting the catheter more heavily supports a “catheters last” approach to improve quality in this critical area.

While the rulemaking process is an important tool in soliciting feedback, the discussion around weighting measures may require a more interactive approach. We are not proposing a formal technical expert panel, but rather that CMS engage in less formal discussions with members of KCP and the kidney care community to undertake a more thorough review and update of the measures and their weights prior to the next annual update of the QIP. Such a review would include the opportunity for multi-stakeholder feedback on the importance of the QIP measures and a quantitative analysis of the reliability and improvement opportunity for each measure. It would provide CMS and the community a chance to engage more freely without the confidentiality restrictions imposed through rulemaking.

Given these concerns and recommendations, KCP asks that CMS not finalize the proposed weights and instead work with the kidney care community in the coming months to develop weights that reflect the basic principles of clinical value and importance to patients.

B. KCP Response to the Request for Information on Quality Indicators for Home Dialysis Patients

1. KCP Recommends that CMS Adopt the Set of Home Dialysis Measures Developed by the Kidney Care Quality Alliance (KCQA) and Support the Adoption of a Patient Satisfaction Survey for Home Dialysis Patients.

KCP asks that CMS adopt the following two measures developed by the KCQA and that have been submitted to the National Quality Forum (NQF) for endorsement.

- The home dialysis rate measure: percent of all dialysis patient-months in the measurement year in which the patient was dialyzing via a home dialysis modality.
- The home dialysis retention measure: percent of all new home dialysis patients in the measurement year for whom ≥ 90 consecutive days of home dialysis was achieved.

The KCQA convene a group of technical experts in the area of home dialysis, including patients, nephrologists, nephrology nurses, dialysis facility clinical staff, and home dialysis manufacturers. The KCQA asked these experts to develop measures that would provide individuals with kidney failure, their families, care partners, and health care professional with a clear understanding of the performance of dialysis facilities in expanding access to home dialysis modalities. While having a rate measure was the starting point, patients and patient advocates were particularly interested in coupling the rate measure with a retention measure.

KCP supports the expanded efforts within the Biden-Harris Administration and the kidney care community to encourage greater selection of home dialysis modalities. While these initiatives have the potential to dramatically change nephrology and dialysis care in the United States, individuals with kidney disease and other stakeholders have raised concerns that the unilateral focus on home dialysis growth in a healthcare system not adequately prepared for such an influx may lead to suboptimal outcomes and have unintended, prolonged negative effects on home dialysis selection. Incentivizing a rapid rise in the use of home dialysis in the absence of safeguards and a sufficiently robust infrastructure to support such growth could lead to increased technique failure rates. It may also subject many patients to a treatment modality for which they have not received adequate education or training, and may even inadvertently result in infringement on patient choice.

To address such concerns, KCQA's "Home Dialysis Measure Set" has been developed and designed to promote steady, deliberate performance improvement over time by addressing both sides of the home dialysis utilization equation—uptake and retention. The set pairs a "core" Home Dialysis Rate Measure with a "guardrail" Home Dialysis Retention

Measure, intended to counterbalance the unopposed incentivization of home prescription that might occur if a rate measure were implemented alone, minimizing the potential adverse consequences of unchecked home dialysis growth. The retention measure will also allow providers to more readily assess the success of their efforts to create a sustainable home program through appropriate patient education, preparation, and support, and to apply targeted quality improvement interventions as needed.

We encourage CMS to adopt these measures as the basis for monitoring and assessing the quality of care delivered to patients who receive home dialysis.

In addition, KCP continues to support patient satisfaction measures that would capture feedback from home dialysis patients. We are aware of ongoing work to develop a tool that would be used by home dialysis patients. Our members are ready to support this effort and encourage CMS to provide assistance to support this tool as well.

2. KCP Recommends Several Policy Changes to Support More Equitable Access to Home Dialysis across Different ESRD Populations.

Since its founding, KCP has promoted empowering patients to select the treatment modality that is best for them as individuals. One of the organization's first and most important policy achievements was the establishment of the Kidney Disease Education (KDE) benefit to improve patient education prior to starting dialysis. It has served an important role in empowering more patients to make their own choice of treatment modality. However, more needs to be done, as HHS recognizes. Empowering each patient and increasing his/her ability to select the treatment modality that is best for that individual requires a commitment from the federal government to:

- Expand access to CKD screening;
- Incentivize medical professionals to specialize in nephrology;
- Provide CKD treatment and education earlier in the progression of the disease and before an individual's kidneys fail; and
- Address patients' socio-economic problems that drive patients' decision-making.

CMS should encourage patient education and choice. It is important that Medicare adequately reimburse providers for the services provided. Additionally, we encourage CMS to work to address the major barriers to increasing home dialysis that are based on SDOH to provide patients with true choice. KCP believes it is important to find ways to address barriers to home modalities, such as housing instability, access to care partners, and earlier education and screening.

a. Increasing Awareness and Screening

The vast majority of individuals with kidney disease remain unaware they have the disease. Only 7.2 percent were aware of their kidney disease between 2003 and 2006, and between 2015 and 2018, the percentage who were aware increased only to 12.1 percent. Those with more advanced stages of kidney disease were also more likely to be aware than those with earlier stages, although recognition was still low even in stage 3 (16.9 percent, compared with 61.9 percent for stage 4 and 86.3 percent for stage 5 in 2018).⁴ CKD Stage 3b (eGFR 30-44) is a crucial stage when intervention can help slow the progression of the disease. Interventions during stage 4 are also very important with regard to the preparation for kidney replacement therapy modality selection, preparing for a transplant, or selecting conservative care. If patients do not know they have CKD at these stages, these interventions do not occur.

Screening for CKD is essential for public health. In contrast to 10 years ago, when treatments were more limited for CKD, we have added many new agents to the armamentarium that are proven to reduce progression of CKD. These include SGLT2 inhibitors and novel mineralocorticoid receptor blockers. Critically, screening for CKD must include not only eGFR but also markers of kidney damage, including albuminuria/proteinuria. In addition, we have learned during the pandemic that understanding an individual's kidney disease status can be critical to protecting against viruses, including COVID-19.

One of the first step in addressing this health care inequality is diagnosing CKD in individuals as early as possible so that they can begin the process of managing their disease. Since 2012, the clinical community generally and the kidney care community in particular has learned more about how to effectively screen individuals for CKD. There have also been significant strides in treating early stages of CKD. Yet, without screening, these effective interventions are unlikely to be tried or prescribed because CKD has no distinguishing symptoms. A clinical test is needed to diagnose the disease. Our clinical experts also recommend that screening for CKD include the presence of albuminuria.

KCP remains committed to working with the federal government to find ways to address the challenges that individuals living with kidney disease face. Getting an accurate and timely diagnosis is one of those challenges. To that end, KCP strongly supports H.R. 4065/S. 1971, "The Chronic Kidney Disease Improvement in Research and Treatment Act of 2021" introduced in the House by Representatives Terry Sewell (D-AL) and Vern Buchanan (R-FL) and in the Senate by Senators Ben Cardin (D-MD) and Roy Blunt (R-MO). Section 101 of this legislation seeks to add CKD screening to the annual wellness benefit to allow Medicare beneficiaries at risk for kidney disease and kidney failure to learn if they in fact have the disease and seek treatment to slow the progression toward kidney failure or better prepare for transplant or dialysis.

⁴*Supra*, note 9.

In addition to extending these screening efforts in the Medicare program, given the number of individuals with kidney disease who are low-income, we ask that CMS work with State Medicaid Agencies to extend these screenings within the Medicaid programs.

b. Incentivize Placement of Home Dialysis Accesses

We also recommend that CMS support nephrologists by increasing the home dialysis training fee to reflect the cost-of-living increases that have occurred since it was established. The federal government needs to work to eliminate the SES and SDOH barriers that prevent patients from being empowered to make their own choices.

CMS should also create incentive payments for nephrologists and facilities linked to home dialysis adoption. First, it could increase the physician payment for home training from \$500 (which has been the rate for more than 30 years) to \$1750, which is the \$500 amount updated for current dollars. The initial \$500 could be paid at the outset, while the increase of \$1250 could be paid out after a patient has completed six months of successful home dialysis treatments. Second, it could establish bonus incentive payment for surgeons, hospitals, and surgery centers to bring reimbursement for PD catheter placement in line with AV Fistula reimbursement.

CMS can also continue to explore waivers to fraud and abuse laws, that create unnecessary silos in the provision of care and stop care coordination services from taking place.

c. Expanding Access to the KDE Benefit

Education for patients is also an essential component of improving equity in modality choice. As a first step, KCP believes it is important to establish aligned requirements for all providers to talk with patients about their modality options at every stage in the process, particularly prior to starting dialysis. As many in the community recognize, individuals who learn they have kidney disease, especially in the later stages, experience significant depression and may not always process immediately the information they are receiving. This is the very time that most patients are entering a dialysis facility and being provided with their first educational sessions. It can often be too late for patients to make a modality decision. Patients with little to no nephrology care prior to “crashing” into dialysis will often be suffering from chronic uremia and volume overload, which again can make it difficult to receive and process “early” modality choice education. To expand educational outreach, we recommend creating consistent, clear, non-branded materials accessible to patients with differing levels of health literacy, for patient advocacy groups use with patients.

Another step to address the problem is to expand the existing KDE benefit. Currently, the KDE benefit provides limited reimbursement and support for six sessions to

patients with Stage 4 CKD. Current law restricts the health care professionals who can provide these services to physicians, physician's assistants, nurse practitioners, or clinical nurse specialists; hospitals, critical access hospitals (CAH), comprehensive outpatient rehabilitation facilities (CORF), home health agencies (HHA), or hospices that are located in a rural area; or hospitals or CAHs paid as if they were located in a rural area.⁵ The program should be expanded to allow more patients to access KDE services and permit more providers to provide the services. It also should be expanded to include virtual education using telehealth platforms. "The Chronic Kidney Disease Improvement in Research and Treatment Act of 2021" introduced in the House and the Senate⁶ would allow dialysis facilities to provide kidney disease education services and expand access to these services to Medicare beneficiaries with Stage V CKD not yet on dialysis. We encourage the Administration to prioritize passage of this provision. CMS should also look at addressing the underfunding of this benefit, which has been highlighted as one of the reasons so few eligible providers have provided KDE services.

d. Addressing SDOH Barriers to Home Dialysis

Many of the concerns KCP has already identified, such as the lack of access to screening programs and early interventions, limited or no access to primary care physicians and nephrologists, and low socioeconomic status all play a role in the differing rates of home dialysis selection by people from communities of color. These barriers often mean that Black and Brown individuals do not realize they have kidney failure until their kidneys stop working. At that point, they may feel bombarded by information as they try to understand their disease and prognosis. They may be in denial, lose hope, or become controlled by their fears.

Beyond these challenges older adults, adolescents, people with low income and educational levels, and racial and ethnic minorities are disproportionately affected by lower health literacy, as well as cross-cultural communication and language barriers. We encourage CMS working with the HHS Office for Civil Rights (OCR) and the CDC to provide meaningful assistance to clinicians, social workers, and families by creating and disseminating documents that provide information in an easy-to-understand manner and in many languages. These documents could also be designed to allow patient organizations or other trusted voices within the individuals' communities to brand them as their own. Patients want to hear the information from trusted voices in their communities also. Providers also need financial support to provide these services in some instances as well.

In addition, CMS could work with patient advocates and community leaders to address financial concerns patients face, particularly those in Black and Brown communities. Home dialysis patients often need the support of their employer to dialyze at

⁵42 CFR § 410.48.

⁶In the Senate, Senators Ben Cardin (D-MD) and Roy Blunt (R-MO) have introduced the legislation as S. 1971, while in the House Representatives Terri Sewell (D-AL) and Vern Buchanan (R-FL) have introduced it as H.R. 4065.

home, but often patients who are Black or Brown fear that lack that support and cannot afford to put their job at risk. Some patients who cannot work fear that home dialysis will result in them losing access to disability insurance. More assistance is needed to reach out to these patients so that they understand their rights. Patients need this support outside of their dialysis providers and nephrologists as well.

C. KCP Continues to Support the Agency’s Efforts to Address Inequities in Health Care, but We Are Concerned with the Proposed Integration of Two Health-Related Social Needs (HRSNs) Screening Measures into the QIP Measure Set.

As a threshold matter, KCP reiterates our request that CMS provide the specifications for all measures proposed for use in the QIP. Of particular concern in this regard is our inability to review the proposed new HRSN screening measure specifications. Absent the detailed specifications and a thorough description of how CMS intends to implement these measures into the QIP, we can neither fully consider the proposal nor provide informed comments. Given the unprecedented nature of these measures and the unknown risks and benefits of their adoption into a penalty-based program, we note that NQF review would also be of particular importance and has not yet occurred.

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 and Support for Underserved Communities Through Government,”⁷ patients with kidney disease are disproportionately from socioeconomically disadvantaged communities and experience inequities in the delivery of health care. KCP, thus, continues to support CMS’s efforts to assess and account for social risk⁸ factors in the ESRD QIP Program 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 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 HRSN screening measures do not strike that balance. Even with the limited information provided, we anticipate that use of the proposed HRSN screening measures in a penalty-based program such as the QIP might in fact perpetuate the very disparities CMS is attempting to address.

⁷ 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.). <https://kidneycarepartners.org/wp-content/uploads/2021/08/KCP-Health-Equity-OMB-Response-2021-Final.pdf>. (Accessed August 2, 2022.)

⁸ 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.

The proposed *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, while the proposed penalty structure is not clearly communicated in the rule, penalties for poor performance on the *Screen Positive* measure would undoubtedly disproportionately and paradoxically impact the most financially vulnerable facilities treating the most socially and medically disadvantaged patients.

Additionally, while measure specifications were not provided, it appears that the metrics would require use of a specific instrument, the *Accountable Health Communities Model Screening Tool*,⁹ an HRSN survey used in a pilot program in an unrelated healthcare setting.¹⁰ Moreover, both the screening instrument and the related fielding requirements for the referenced AHC HRSN Tool are complex and might be expected to be considerably burdensome to both patients and providers, and the instrument itself has not been reviewed by NQF to provide assurance that the survey's psychometric properties are sufficient to support its use in a penalty-based accountability program. In the absence of such evidence, the proposal to incorporate the measures in the QIP cannot be fully assessed by stakeholders and is thus premature.

KCP has consistently supported a number of alternative approaches to addressing persistent health inequities in ESRD care. As detailed in our July 2021 OMB letter,¹¹ we have asked CMS to examine specific QIP measures to determine whether adjustment for social risk factors might improve the ability to differentiate true differences in performance between facilities. Likewise, we support the use of stratification of quality measures to allow health care providers and other stakeholders to identify and prioritize differences in care, outcomes, and experiences across the different racial and ethnic groups. Unlike risk adjustment, which can mask real variations in care and outcomes across different groups, stratification allows providers to better understand the experiences of patients from socioeconomically disadvantaged communities and develop and implement equity-focused practices to address disparities.¹² Finally, KCP has sought to work with the federal

⁹ See Center for Medicare and Medicaid Innovation. "The Accountable Health Communities Health-Related Social Needs Screening Tool." (2017.) <https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf>. (Accessed August 2, 2022.)

¹⁰ See Centers for Medicare and Medicaid Services. "Accountable Health Communities Model." (2022.) <https://innovation.cms.gov/innovation-models/ahcm>. (Accessed August 2, 2022.)

¹¹ *Supra* note 1.

¹² See Advancing Health Equity. "Using Data to Reduce Disparities and Improve Quality." <https://www.aha.org/center/market-insights/leveraging-data/using-data-reduce-health-disparities-and-improve-health-equity>. (Accessed June 22, 2021.)

government to remove barriers to care, many of which center around socio-economic issues. With this goal in mind, we again encourage CMS to collect social determinant of health data using Z-codes to account for and report on the most common non-clinical barriers to home dialysis, including housing or financial insecurity, minimal caregiver support, other mental and certain physical illnesses, or advanced age to provide information about these barriers and develop policies to overcome them and to be able to set target rates of home dialysis adoption.

D. KCP Response to the Request for Information on Overarching Principles for Measuring Healthcare Quality Disparities across CMS Quality Programs

KCP is pleased to see that CMS is moving forward with its work to stratify quality measures. We appreciate that so many of KCP's comments and recommendations from the RFI in last year's rulemaking have been incorporated into this RFI. We agree that stratifying quality measures is one approach to help close the health equity gap, especially for individuals with kidney failure. In our comments on the RFI in the CY 2022 ESRD PPS proposed rule, we identified specific measures in the ESRD quality programs that should be adjusted to advance health equity. We also identify certain SDOH / SES factors that could be used to support stratification of quality measures, such as dual eligibility/LIS status, race and ethnicity, geographic residency, and insurance status.

We also emphasized the importance of making sure that these data elements are available and accessible by providers to allow for them to use the data to improve outcomes. For example, while they have data on dually eligible beneficiaries, race, insurance, and geography, other elements such as LIS status and income are not accessible even though CMS could provide this information. If a patient level SDOH descriptor is needed, KCP has also suggested using Z-codes to support gathering additional information to address gaps in programs due to health inequities. Ideally, CMS would share Z-code data from all sites of care for dialysis patients, not only the facilities. We support additional work with these codes and others to identify other data points, such as the geographic (no patient level) Social Deprivation Index (SDI), that could be used to create better estimates that would permit the stratification of measure data to eliminate disincentives that could be intentionally created without such adjustments. We also agree that these data elements be subject to existing privacy and security requirements to protect the integrity and validity of the data.

It is difficult to advocate for one method or another without understanding the context for how the data will be used. Given the labor crisis we raised in our August 4th letter, we ask that CMS balance burden of additional reporting with incremental data collection. In light of the current situation, KCP prefers using data elements already being gathered today over a new patient level survey.

We recommend the CMS establish an open and transparent process as it reviews the responses to the most recent RFIs and works with NQF and other organizations to allow for an ongoing community dialogue as it develops data options as well. The importance and magnitude of this project suggest the need for processes that allow for greater interaction and dialogue than are permissible during rulemaking.

In the sections below, KCP offers an initial set of comments related to the overarching principles highlighted in the Proposed Rule. However, the complex nature of these issues warrants more attention than a 60-day comment period will allow. Therefore, we would like the opportunity to continue engaging with CMS beyond this comment period to update and augment the comments included below.

1. Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification in ESRD QIP

KCP fully supports the CMS goal of “developing methods to measure disparities in care... to provide actionable and useful results to dialysis providers.”¹³ As we have noted in previous comment letters, providers need measures that are actionable and accessible as tools to address unmet need, gaps in care, and improve outcomes. Generally speaking, KCP supports measures that allow for both within-provider disparities and across-provider disparities. However, each measure would need to be assessed to determine if one or both approaches is appropriate. In addition, KCP would not support across-provider disparities measures that rely upon rank order, bell-curves, or other methodologies that mask actual provider performance. Assessing quality performance for closing health equity gaps requires a transparent and accurate presentation of individual providers’ performance when compared to that of other providers.

2. Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting

Consistent with previous recommendations, KCP is pleased that CMS has outlined specific criteria that it plans to use for selecting and prioritizing measures for disparity reporting. We provide our initial, general comments below and request the opportunity to provide more specific comments in the near future.

- *Prioritize validated clinical quality measures.* KCP continues to support the use of measures that are valid and reliable based on accepted measure development standards. We also have prioritized the use of clinical outcome measures over reporting measures since the inception of the ESRD QIP and in our support of the measure development of the Kidney Care Quality Alliance. Thus, we agree that measures selected for disparities reporting should be those that are valid and reliable. We also ask that CMS clarify that the measures would also be

¹³87 Fed. Reg. at 38588.

actionable by facilities, which seems implied from other statements throughout the RFI.

- *Prioritizing Measures with Identified Disparity in Treatment or Outcomes Among Participating Facilities for Selected Social or Demographic Factors.* KCP supports the criterion that the measure be supported by evidence of underlying healthcare disparities in the procedure, condition, or outcome being measured. We agree that peer-reviewed research reviews should be an important component of this review, but there is a dearth of research in the advanced CKD population, including few randomized control trials, which results in a lower level of evidence available to guide many of these measures. Thus, we encourage CMS to also engaged actively with KCP and others to identify clinical practice guidelines and similar types of material to support efforts to prioritize measures.
- *Prioritize Measures with Sufficient Sample Size to Allow for Reliable and Representative Comparisons.* KCP supports this criterion as well. In previous letters, we have raised concerns that the current minimum number of cases being set at 11 is simply too low to address the problem of creating random outcomes. To that end, we agree that measures selected should have a sufficient sample size to allow for reliable outcomes and comparison.
- *Prioritize Outcome Measures and Measures of Access and Appropriateness of Care.* In theory, we agree that it is important to understand gaps in access and obtaining appropriate care. However, it is not clear to us based on the preamble what these types of measures would be. Therefore, we ask that CMS provide more information about this criterion and offer additional opportunities for comments before finalizing it.

3. Principles for Social Risk Factor and Demographic Data Selection and Use

KCP appreciates that CMS recognizes in the preamble the numerous non-clinical drivers of health associated with patient outcomes, including social risk factors such as socioeconomic status, housing availability, and nutrition, as well as marked inequity in outcomes based on patient demographics such as race and ethnicity, being a member of a minority religious group, geographic location, sexual orientation and gender identity, religion, and disability status. We have also been struggling to identify sources of social risk and demographic information. We continue to believe it is important that data should provide patient-level information when supporting efforts such as the stratification of ESRD quality measures.

While new sources are being developed, there are existing sources that could be used to stratify measures by: income (*e.g.*, dual eligibility/low-income subsidy status); race and ethnicity; insurance status at the initiation of dialysis; and geographic area of

residence. The elements of race and ethnicity would need to be self-reported by patients; income, insurance, and geographic areas are data that we understand CMS already has and could share with providers. Using these data elements (while others are developed in consultation with stakeholders) would allow the stratification work to move forward more quickly. It also has the benefit of avoiding additional reporting burdens on patients and providers at a time when there are fewer resources available for such efforts.

4. Identification of Meaningful Performance Differences

CMS proposes four different options for reporting measures in a meaningful way: (1) statistical differences; (2) rank ordering and percentiles; (3) thresholds; and (4) benchmarking. KCP has long opposed rank ordering and percentiles because they distort the actual performance of facilities by masking the true relationship between and among facilities. For example, analyses prepared for KCP by Discern related to the Five Star program demonstrated how the rank order methodology exaggerated differences of sometimes less than 1 percentage point that led to several star differences between facilities that were by all other accounts relatively equal in terms of performance. Such results led to confusion among patients and providers creating distrust in the overall system. To ensure that stratification comparisons are actionable and reliable, we strongly urge CMS to avoid rank order and percentiles to avoid the problems of the past.

Generally, we have supported benchmarking, thresholds, and statistical difference methodologies. However, before we could endorse their use in this context, we would want to better understand the specific methodologies and other details about their implementation. It is important that as CMS considers these methodologies, the agency engage actively with KCP, patients, and providers to ensure that the benchmarks or thresholds are clinically reasonable and appropriately balance promoting population health with the need for individualized care. For example, setting benchmarks or thresholds using only statistics could result in a system that incentivizes clinically inappropriate situations, such as forcing individuals to try to grow fistulas when a graft or even a catheter might be the most appropriate option for an individual patient.

We also encourage CMS to work with the kidney care community and focus metrics and the public reporting on closing the gap created by the disparities rather than focusing on reporting on disparities more generally. The goal should be to emphasize what facilities are doing to address the disparities in their population. If reported in the wrong way, individuals who experience inequities related to SDOH could find it difficult to receive the services they need.

5. Guiding Principles for Reporting Disparity Results

While KCP has strongly supported public report in the current ESRD quality programs, identifying specific facilities in stratification reporting could lead to unintended consequences. For example, gaps in treatment due to factors beyond a facility's control

could become the basis of legal proceeding that even if proven false still require substantial resources to defend against and could erode trust among patients and staff. We believe an initial approach focused on confidential reporting at the facility level and perhaps de-identified aggregate reporting could be the appropriate place to start. However, KCP would like to work closely with CMS to consider options for provide publicly available data at some point from this initiative as well.

We also ask CMS to work closely with KCP and the community as it defines and reports these elements. For example, it will be important to address how broad terms, such as ethnicity, are defined and used. There are many different ethnicities encompassed by terms such as Hispanic or Black. These differences may be important when trying to close gaps in treatments. Similarly, the different SDOH may interact with each other or other SES factors, such as health literacy, in ways that are important to identifying and resolving gaps in treatments. We are committed to working with CMS to make sure this information and the measurers created are targeted to meet the Administration's and the community's goals to close such gaps.

II. ESRD ETC Model Comments

A. KCP Is Concerned with the Proposed Performance Payment Adjustment Achievement Scoring Methodology

KCP appreciates that CMS continues to refine the ETC model. However, we remain concerned that the underlying methodology needs to be revisited as the model shift toward the penalty phase. Despite aggregating within HRRs, there still appears to be counting issues with regard to facilities aggregating patients into centralized facilities, particularly around home dialysis. There is not a one-to-one relationship between home and in-center facilities. Greater transparency with regard to how this practice is being taken into account would allow the kidney care community to work with CMS to identify potential solutions. This problem is only one of a handful on which we ask CMS to engage with KCP and its members to ensure that the methodology works properly and supporting the goals of the ETC program.

We are also concerned that the success of the model is being devalued by the artificial comparison with the "control" group. As we noted in previous letters, facilities and nephrologists in the control group are not maintaining the status quo while the ETC Model progresses. The pandemic has only made this confounding issue more prominent. Eliminating the comparisons and focusing on benchmarking might be one way to address this issue, but we request that CMS engage in an active dialogue with the community and participants during the coming weeks to address such issues.

We also remain concerned that launching the ETC and KCC Model at the same time will also confound the results, making it difficult to assess which of the policies actually led to the final results.

KCP remains committed to supporting the ETC Model and wants it to succeed. However, as it moves toward the penalty phase, we ask that CMS re-engage with the kidney care community and participants.

B. KCP Supports Expanding Patient Access to the KDE Benefit and Opposes Policies that Limit Those who Can Provide Services because They are Likely to Perpetuate the Low Utilization of the Benefit.

Since its founding, KCP has promoted empowering patients to select the treatment modality that is best for them as individuals. KCP aggressively advocated for the creation of the KDE benefit to improve patient education prior to starting dialysis. We continue to promote policies to improve its utilization so that patients have the information they need to make informed decisions. While the KDE benefit needs to be improved, it has served an important role in empowering more patients to make their own choice of treatment modality, including expanding access to transplants and home dialysis.

KCP appreciates the flexibilities CMS established for the KDE in the ETC Model to broaden the availability of these services. However, we do not support policies that narrow the benefit. While we understand the theoretical concern that arrangements between dialysis facilities and ETC participants could impact referrals, there is no evidence that CMS cites showing that allowing ETC participants to engage in these arrangements has been a problem. We are concerned that a restrictive policy of this nature will only perpetuate the infrequent use of the KDE services. KCP also agrees with CMS that it would be practically difficult to try to micromanage conversations between clinical staff and patients during KDE sessions, especially given that there is no evidence that KDE benefits have led to steering. To expand educational outreach while addressing theoretical concerns, we recommend creating consistent, clear, non-branded materials accessible to patients with differing levels of health literacy, for patient advocacy groups use with patients.

KCP believes providing patients with access to clinical experts regardless of where they are employed should be the priority of CMS policies related to the KDE benefit. If a problem were to occur, we would welcome the opportunity to find ways to address it; but until that time CMS should focus on increasing access.

C. Publication of Participant Performance

KCP remains committed to providing transparent, meaningful data on performance to individuals receiving dialysis, their care partners, and other stakeholders in the kidney care community. However, we are concerned that the proposal to publish ETC participant performance may be confusing for stakeholders. It is not clear how the aggregation of individuals relying upon home dialysis will be accounted for in the performance publication. Before CMS provides this information, we recommend that CMS provide a more detailed description about the way the data will be presented and ensure a preview

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period before any information is release. KCP recommends that CMS engage in more discussions with Participants before finalizing the publication of participant performance plan.

III. Conclusion

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

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Butler', with a long horizontal flourish extending to the right.

John Butler
Chairman

cc: Dr. Lee Fleischer, Chief Medical Officer and Director, CCSQ
Dr. Michelle Schreiber, Director, Quality Measurement & Value Based Incentives Group, CCSQ

Appendix: 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
DaVita
Dialysis Patient Citizens
DialyzeDirect
Dialysis Vascular Access Coalition
Fresenius Medical Care
Greenfield Health Systems
Kidney Care Council
NATCO
Nephrology Nursing Certification Commission
Otsuka
ProKidney
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma