



August 26, 2021

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

Re: CMS-1749-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” (Proposed Rule). This letter focuses on the ESRD QIP program and the request for information related to that rule. Our comments on the ESRD PPS, AKI, and ETC Model will be provided in separate letters.

KCP is an alliance of more than 30 members of the kidney care community, including patient advocates, health care professionals, providers, and manufacturers organized to advance policies that support the provision of high-quality care for individuals with chronic kidney disease (CKD), including those living with End-Stage Renal Disease (ESRD).

KCP wants to thank CMS for working with KCP members during the pandemic. As the Centers for Disease Control and Prevention (CDC) has recognized, patients with Chronic Kidney Disease (CKD), especially those with Stage 5 kidney failure, are at a heightened risk of contracting COVID-19. Thus, finding ways to promote care in the home through expanding telehealth services and access to laboratory testing in the home are important steps to reduce the risk of infection. In addition, allowing facilities to have the flexibility to implement programs to help patients who require in-center hemodialysis, even after diagnosed with COVID-19, has helped to ensure that all patients receive the care they need during these difficult times. Most importantly, we appreciate the Biden-Harris

Administration's decision to allocate vaccines directly to dialysis facilities to allow them to leverage their thrice weekly contact with patients and encourage them to be vaccinated.

Even with these efforts, the effect of the pandemic on people with kidney disease, care partners, and providers has been enormous. As described in detail below, KCP appreciates that CMS has recognized the challenges of the pandemic and has proposed solutions to address the potential negative impact on the ESRD QIP for years based on data from CY 2020. We fully support these proposals.

In addition, we strongly support the Administration's efforts to address inequities in health care. As we described in detail in our July 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," patients with kidney disease are disproportionately from communities of color and experience inequities in the delivery of health care. Throughout this letter, KCP makes recommendations that we believe will help address this systemic problem.

However, the modifications to the ESRD QIP alone are not enough. The systemic barriers to accessing basic health care likely play a substantial role in these individuals developing kidney disease and progressing to kidney failure. The leading causes of CKD and ERSD are hypertension, diabetes, and obesity. Black and Hispanic individuals are diagnosed with these diseases more than other Americans.¹ We know from several years of research that people of color have greater difficulties accessing preventative care and chronic disease management services.² It is very likely that the challenges these individuals faced when trying to access basic health care services resulted in chronic diseases, such as diabetes, obesity, and heart disease, not being fully managed, which led to the development of kidney disease. KCP renews its commitment to work with CMS and other federal agencies to find ways to address these challenges that exist prior to an individual's kidneys failing.

In addition, KCP since 2005 has led the kidney community in its efforts to shift to a patient-centered, quality-based approach to providing kidney care in America. Through the Kidney Care Quality Alliance (KCQA), our members have developed measures, navigated them through the National Quality Forum's (NQF) endorsement and maintenance processes, and advocated for their inclusion in the Medicare ESRD QIP and other quality programs. In the Spring of 2021, KCQA renewed its measure development agenda. Led by Drs. George Arnoff and Keith Bellovich as the co-chairs of the KCQA

¹ Richard V. Reeves & Faith Smith. "Up Front: Black and Hispanic Americans at Higher Risk of Hypertension, Diabetes, and Obesity: Time to Fix Our Broken Food System." *Brookings*. <https://www.brookings.edu/blog/up-front/2020/08/07/black-and-hispanic-americans-at-higher-risk-of-hypertension-diabetes-obesity-time-to-fix-our-broken-food-system/> (Aug. 7, 2020). accessed June 28, 2021.

²Kenneth E. Thorpe, Kathy Ko Chin, Yarira Cruz, *et al.* "The United States Can Reduce Socioeconomic Disparities by Focusing on Chronic Diseases." *Health Affairs* (Aug. 17, 2017) <https://www.healthaffairs.org/doi/10.1377/hblog20170817.061561/full/>. accessed June 20, 2021.

Steering Committee, KCQA is developing measures in the domains of home dialysis, transplant, anemia management, bloodstream infection, and bone mineral metabolism. Each of these domains constitutes care priorities for patients. Current measures in these domains lack validity, reliability, and/or actionability. They do not provide accurate information to people living with kidney disease or the information providers need to improve outcomes. We look forward to working closely with CMS to bring these measures forward and integrate them into the ESRD QIP, Facility Compare/Five Star, and the ETC Models. Our comments in this letter offer recommendations about how to address the short-comings of the current measures in these domain areas that are part of the ESRD QIP.

KCP appreciates the ongoing collaborative partnership with CMS to promote transparency, accountability, and high-quality patient-centered care for the people living with kidney disease whom we serve. We look forward to working with you on this year's rulemaking.

I. KCP supports the Extension of the Extraordinary Circumstances Exception (ECE) previously granted for the ESRD QIP and notification of ECE due to ESRD Quality Reporting System problems.

KCP appreciates that CMS has recognized the challenges related to data reporting during the pandemic, as well as the issues related to the submission of the data through the ESRD Quality Reporting System (EQRS). We fully support the blanket extension of the CY 2020 clinical reporting deadlines. Under this extension, facilities will have until September 1, 2021, to submit September through December 2020 ESRD QIP clinical data. Based on our current understanding of the status of EQRS, we anticipate that an additional extension may be required potentially through the end of 2021. If that were the case, we support the decision to issue notifications through the guidance mechanisms CMS outlines in the Proposed Rule. As noted below we also support the proposals not to score or award any Total Performance Score (TPS) to any facility or reduce payment to any facility in PY 2022 because of the system issues experienced during the implementation of the EQRS.

II. KCP supports the proposed flexibilities for the ESRD QIP in response to the COVID-19 PHE.

As noted in the introduction, KCP appreciates the continued engagement with CMS and the agency's efforts to eliminate barriers that make delivering care during a pandemic difficult. The proposals outlined in this section of the Proposed Rule are crucially important, and KCP encourages CMS to finalize them as proposed with a few modifications.

A. KCP supports the proposed Measure Suppression Policy for the Duration of the COVID-19 PHE.

KCP shares the CMS's concerns "that the ESRD QIP's quality measure scores that are calculated using data submitted during the PHE for COVID-19 will be distorted and will

result in skewed payment incentives and inequitable payments, particularly for dialysis facilities that have treated more COVID-19 patients than others.”³ We appreciate the decision not to penalize dialysis facilities based on distorted data and that do not reflect “the quality of care that the measures in the ESRD QIP were designed to assess.”⁴

KCP agrees with the Measure Suppression Factors CMS would use as the basis for determining when it would be appropriate to suppress the ESRD QIP measure data.

- Factor 1: Significant deviation in national performance on the measure during the COVID-19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.

KCP supports the adoption of Factor 1. Significant deviation in national performance would indicate a major disruption in the delivery of care that extends beyond the control of dialysis facilities. As we have experienced during the pandemic, COVID-19 specifically has resulted in many of the measures in the ESRD QIP being distorted because of the novel virus itself or the isolation and stay-at-home orders imposed to control the spread of the virus. For example, the lack of clarity as to whether vascular access surgeries were elective surgeries (and thus unavailable) during most of 2020 confused many patients and resulted in fewer fistulas and grafts being placed. Similarly, all-cause hospitalizations and readmissions increased because these measures do not distinguish among the causes for the admission, including whether or not the admission was related to the pandemic.

- Factor 2: Clinical proximity of the measure’s focus to the relevant disease, pathogen, or health impacts of the COVID-19 PHE.

Similarly, KCP supports the adoption of Factor 2. Measures in the ESRD QIP, such as those related hospitalization and readmissions were distorted given that the novel coronavirus resulted in extraordinarily high numbers of individuals who contracted the disease being hospitalized. Similarly, mortality (not an ESRD QIP measure, but a measure in the ESRD Facility Compare/Five Star program) has increased substantially due COVID-19. The placement of fistulas and grafts became more difficult during the pandemic, especially given the conflicting messages about whether these procedures were elective or not during the time when Medicare delayed elective surgeries due to the pandemic. The poorer performance on these measures reflects the impact of the novel coronavirus, not the quality of care provided through dialysis facilities.

- Factor 3: Rapid or unprecedented changes in:

³End-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, 86 *Fed. Reg.* 36322, 36350 (July 9, 2021).

⁴ *Id.* at 36350.

- Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or
- The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

KCP also supports Factor 3. In many ways, it is difficult to believe that only a little more than a year has passed since the World Health Organization (WHO) declared COVID-19 to be a pandemic. The last 18 months have demonstrated how nimble and resilient our health care system is in many ways, but it has also exposed dangerous inequities and gaps. The rapid changes in the medical and public health communities' understanding of the transmission of the virus to the unprecedented development of effective vaccines have shown how quickly the scientific, medical, and public health communities can come together to address an emergency situation. The rapid changes and laser focus on protecting people with kidney failure from exposure and severe complications demanded providers full attention. As dialysis facilities, nephrologists, and nurses struggled to adapt to the changing guidelines and practices, the ESRD quality measures garnered significantly less attention. Protecting patients and staff understandably became the first priority.

- Factor 4: Significant national shortages or rapid or unprecedented changes in:
 - Healthcare personnel;
 - Medical supplies, equipment, or diagnostic tools or materials; or
 - Patient case volumes or facility-level case mix.

Finally, KCP also supports Factor 4. We are proud of the way the kidney care community pulled together to share protective personal equipment (PPE), found ways to cohort patients to protect them from exposure to the virus, fought to allow dialysis patients to be vaccinated at dialysis facilities, and undertook many more steps to address the unprecedented shortages in medical supplies during this pandemic. However, these shortages and changes in patient volume and mix has had a dramatic impact overall that affected the outcomes of many quality measures and the ability to report them.

B. KCP supports the proposal to suppress four ESRD QIP Measures for PY 2022 and suggests the suppression of two additional measures.

KCP agrees with the proposal to suppress the four ESRD QIP Measures outlined in the Proposed Rule. As described above and in the preamble to the Proposed Rule, the Standardized Hospitalization Measure (SHR), Standardized Readmissions Ratio Measure (SRR), In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration Measure, and the Long-Term Catheter Rate Measure each experienced significant deviation in national performance during the pandemic and were affected by the close clinical proximity of the measure to the impacts of COVID-19, the rapid and unprecedented changes in clinical guidelines and care delivery due to COVID-19,

and national shortages of personnel, medical supplies and equipment, and changes in facility-level case-mix.

In addition to finalizing the suppression of these measures, KCP suggests that CMS also suppress the Hemodialysis Vascular Access: Standardized Fistula Rate Measure, which measures the use of an arteriovenous (AV) fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month. The AV Fistula Rate Measure is linked to the Long-Term Catheter Reduction Measures. As such, we believe that there would be a significant deviation in national performance on the measure during the PHE that would likely be significantly worse when compared to historical performance during 2019. The reason is that the AV Fistula Rate Measure assesses the successful placement and use of an AV Fistula. During the pandemic, CMS delayed all elective surgeries. For several months, it was not clear and nothing in writing was published indicating that a fistula placement was not an elective surgery. Many patients feared entering medical facilities unless it was absolutely necessary. This fear was well-founded, especially during the early months of the pandemic when there was a shortage of PPE and other elective procedures were paused. The rapidly changing understanding of COVID-19 and how it spread as an aerosol only made the situation more precarious for patients. Given these facts, we request that the AV Fistula Rate Measure be suppressed as well.

We also request that CMS suppress the Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure, which measures the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period. Studies have demonstrated that the COVID-19 pandemic had a significantly negative impact on transplant referrals and listing, along with organ donation rates, organ procurement and shipping, and waitlist mortality.⁵ For example, one study using SRTR data compared data on observed waitlist registrations, waitlist mortality, living-donor and deceased-donor kidney transplants (LDKT/DDKT) March 15-April 30, 2020, to expected events calculated from pre-epidemic data January 2016-February 2020. There were few changes before March 15, but after that time, new listings dropped to 18 percent below the expected value (all $p < 0.001$). The researchers found that the decline in new listings was greater among states with higher per capita confirmed COVID-19 cases.⁶ Another study noted that “All UNOS regions reported a decrease in total waitlist additions and transplant surgeries. The largest decreases in total transplants were identified in regions 1, 2, 6, and 9, with regions 2, 7, 8, and 9 noting the largest decrease in waitlist additions.”⁷ Overall, UNOS registry data

⁵Khairallah P, Aggarwal N, Awan AA, Vangala C, Airy M, Pan JS, Murthy BVR, Winkelmayer WC, Ramanathan V. The impact of COVID-19 on kidney transplantation and the kidney transplant recipient - One year into the pandemic. *Transpl Int*. 2021 Apr;34(4):612-621. doi: 10.1111/tri.13840. Epub 2021 Feb 26. PMID: 33545741; PMCID: PMC8013003.

⁶Boyarsky BJ, Werbel WA, Durand CM, et al. Early national and center-level changes to kidney transplantation in the United States during the COVID-19 epidemic. *Am J Transplant*. 2020;20(11):3131-3139. doi:10.1111/ajt.16167.

⁷Cholankeril, George et al. “Early Impact of COVID-19 on Solid Organ Transplantation in the United States.” *Transplantation* vol. 104,11 (2020): 2221-2224. doi:10.1097/TP.0000000000003391

showed an overall 25 percent decrease in waitlist additions in April 30, 2020, when compared to January and February 2020.⁸ While the telehealth waivers helped some patients connect to their transplant waitlist appointments, it did not solve the overall problem of accessing waitlists during the pandemic. Therefore, for reasons similar to those articulated for the four measures proposed to be suppressed for PY 2022, we ask that CMS suppress the PPPW measure for PY 2022 as well.

C. KCP supports the proposed Special Scoring Methodology and Payment Policy for the PY 2022 ESRD QIP.

KCP supports the proposal to apply a special rule for PY 2022 scoring that would result in CMS not calculating achievement and improvement points for any of the measures because of the impact of the pandemic. Given the unprecedented nature of the pandemic, we agree that is appropriate not to calculate a TPS and apply payment cuts. The Congress intended the QIP TPS and attached penalties to incentivize improving performance over time and attaining specified performance standards. The pandemic demanded that facilities and health care providers focus on caring for their patients to reduce infection rate, help manage COVID-19 in those patients who became infected, and work to find ways to protect their staff, especially when they found medical equipment and supplies in short supply. Given the ever-changing information about the disease, how it spreads, how to treat it, and how to avoid further infections, it is appropriate to apply the proposed special rule. Avoiding financial penalties at this time is also important because of the increases in costs associated with managing patient populations during this pandemic, such as the increased costs in PPE and certain shortages in medical equipment and supplies. Allowing the system to stabilize before imposing quality penalties as we hope the pandemic nears an end is an appropriate step for CMS to take.

III. KCP offers practical suggestions to refine the ESRD QIP for PY 2024 to make it more effective at driving quality improvement and more meaningful for individuals relying on dialysis and their care partners.

KCP appreciates that CMS has proposed no additional measures for the PY 2024 ESRD QIP measure set. However, we are disappointed that it has not proposed removing some of the measures as KCP has recommended based on CMS's criteria in previous years. We offer our suggestions again in this letter, highlighting the negative impact retaining these measures will have on individuals receiving dialysis who are already vulnerable to inequities in the health care system. We continue to support maintaining the current QIP structural policies to allow patients, providers, and care partners to compare facility performance year-over-year.

⁸*Id.*

A. KCP recommends that CMS use this rulemaking cycle to reduce the number of measures in the ESRD QIP and revise those measures that are not valid, reliable, or actionable.

KCP remains concerned about the overwhelming number of measures in the ESRD QIP. Too many measures dilute the impact on the individual measures. Recent studies critical of the ESRD QIP bear out this concern. For example, one study concluded that:

As one of the first financial QIPs in healthcare, the ESRD QIP has not achieved the stated goals of the CMS to increase AVF access rates above 68 percent and reduce long-term TDC clinical rates below 10 percent. Systemic disparities in race, geographic region, economic status, healthcare access, and education of providers and patients prevent successful attainment of goal metrics.⁹

Another recent study found “no association between penalization and improvement in specific measures.”¹⁰

These findings highlight several issues have long been of concern to KCP, which include:

- The program includes too many metrics over too broad a range of quality priorities; facilities cannot focus sufficient efforts or resources to address each measure independently.
- Annual penalties are based on a growing number of measures that change frequently, making the program, in effect, a moving quality target that exhausts facility resources and diminishes opportunity to achieve appreciable improvement over time.
- The QIP may levy a disproportionate share of penalties on the most financially-at-risk safety net types of dialysis facilities. Because many of these centers care for the poorest and otherwise underserved communities, this penalty structure may potentiate existing healthcare inequities.
- Many measures included in the QIP do not meet CMS’s own rigorous quality standards:

⁹Shah S, Feustel PJ, Manning CE, Salman L. CMS ESRD quality incentive program has not improved patient dialysis vascular access. *J Vasc Access*. 2021 Jul 5:11297298211027054. doi: 10.1177/11297298211027054. Epub ahead of print. PMID: 34219530.

¹⁰Sheetz KH, Gerhardinger L, Ryan AM, Waits SA. Changes in Dialysis Center Quality Associated With the End-Stage Renal Disease Quality Incentive Program : An Observational Study With a Regression Discontinuity Design. *Ann Intern Med*. 2021 Jun 1. doi: 10.7326/M20-6662. Epub ahead of print. PMID: 34058101.

- Several measures have been empirically demonstrated by CMS as being not statistically reliable (*i.e.*, results cannot be consistently reproduced) or valid (*i.e.*, results are not an accurate representation of the care provided);
- Some measures are not actionable (necessary remedies are not within the control of the dialysis facility) which means that cannot be used to drive quality improvement;
- Other measures are “topped out” (performance is already excellent and there is no room for additional improvement);
- Some are overly burdensome to providers and patients;
- Several measures¹¹ are not endorsed by the National Quality Forum.

To address these concerns and allow the ESRD QIP to mature into an effective value-based purchasing program, we ask that CMS reduce the number of metrics in the QIP, focusing exclusively on measures that matter (*i.e.*, those offering demonstrably valid, reliable assessments of meaningful outcomes or access to specific care processes empirically linked to those outcomes and with sufficient variation to warrant measurement).

Recommended ESRD QIP Measures

- Hospitalization/Readmissions
 - Modify the current measure to be a standardized hospitalization rate measure (current ratio measure modified to a true risk-standardized rate).
 - Modify the current measure to be a standardized readmissions rate measure (current ratio measure modified to a true risk-standardized rate).
- Vascular Access
 - Maintain the catheter reduction measure in the ESRD QIP and shift the Standardized vascular access measure to the Facility Compare/Five Star program.
- Bloodstream infection measure
 - Replace the current measures with one that is valid and reliable, which CDC data show the current measure is not.
- Patient Experience of Care Measures
 - Maintain the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Clinical Measure (fielded in its individually validated sections to reduce patient burden) .
 - Adopt a similar measure for home dialysis patients.
- Anemia Management Measure

¹¹ Only 3 measures in the PY 2022 QIP are fully NQF-endorsed; 5 are “based on” NQF-endorsed measures; 6 have either never been submitted (1), failed endorsement (2), or had endorsement revoked (3).

- Use hgb < 10 g/dL because the current STrR is not actionable because facilities do not have access to the transfusion data.
- Serum phosphorous measure
 - Add because a gap in treatment remains.
- Transplant referral measure, including assistance with first visit
 - Replace with an actional measure because the current measure is not actionable by facilities because transplant centers control the waitlist placement.

The other measures currently in the QIP could be moved to Facility Compare so patients have access them, but the number of measures used to score the QIP would be reduced to allow facilities to focus on a smaller set. This change would dramatically improve the effectiveness of the ESRD QIP, as MedPAC and others have recognized.

In addition, all measures contained in the QIP should be within the realm of the dialysis facility's control (*i.e.*, actionable) and should be NQF-endorsed, when such a measure exists. Finally, adjusting measures for social risk factors, such as dual-eligibility or median household income, may also help reduce the chances that program penalties increase existing disparities.

As noted above, KCP recognizes its role in helping CMS achieve our common goal of making sure that the ESRD QIP an effective value-based purchasing program. The Kidney Care Quality Alliance (KCQA) has convened experts from the kidney care community committed to developing the measures needed to address the problematic measures in the QIP in the domains of bloodstream infection, anemia management, bone mineral metabolism, transplant, and establish a new home dialysis for the ETC Model. We would like to work closely with CMS during this measure development process to make sure that the resulting measures in these domain areas can advance the ESRD QIP and, more importantly, transparency and accountability in the delivery of kidney care to individuals receiving dialysis and their care partners.

In the paragraphs below, we provide specific recommendations for each of the measures proposed to be used in the PY 2024 ESRD QIP measure set.

Standardized Transfusion Ratio (STrR). KCP has asked CMS to eliminate the use of the STrR measure and adopt in its place an outcomes-based measure for anemia management measure, such as Hgb <10 g/dL.¹² The STrR is based on transfusion information to which dialysis facilities do not have access because it is maintained by hospitals or outpatient departments that refuse to provide the information to dialysis facilities even when asked. This fact makes the measure something that facilities cannot act on to improve.

¹²United States Renal Data System. [2020 USRDS Annual Data Report](#): Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.

CMS's own data show very little movement in terms of quality improvement in the use of the STrR during the last three years. The mean of the observed-to-expected ratios across dialysis facilities declined minimally, from 22.5 in 2016 to 21.0 in 2018.¹³

As a result, the measure does little to improve patients' hemoglobin levels, which has a significant impact on their quality of life. Lower hemoglobin levels are associated with the following symptoms including:

- Fatigue or tiredness;
- shortness of breath;
- unusually pale skin;
- weakness;
- body aches;
- chest pain;
- dizziness;
- fainting;
- fast or irregular heartbeat;
- headaches;
- sleep problems; and
- trouble concentrating.¹⁴

Because Black patients often have more difficulty maintaining higher hemoglobin levels, the STrR's lack of actionability can perpetuate the disparity between Black and White patients.

A measure of Hgb < 10 g/dL is preferable. It is actionable and targets the very patients who need help. Hemoglobin values less than 10 g/dL are more prevalent in Blacks, afflicting 27.2 percent and 30.6 percent of Black hemodialysis and peritoneal dialysis patients, respectively, compared to 23.8 percent and 22.7 percent in Whites.¹⁵ While transfusions may be more prevalent in Black dialysis patients, the differences are smaller and result from decisions made in the hospital rather than by the dialysis facility. For example, 23.4 percent of Black dialysis patients received one or more transfusion(s) in 2018, compared to 22.9 percent of Whites.¹⁶

There is both historic and current higher ESA use among Black and Asian patients on home dialysis, while the differences for hemodialysis patients are small. (USRDS Figure 3 by race). For instance, 61 percent of Black and 63 percent of Asian patients on peritoneal

¹³CMS. "2021 National Impact Assessment of the Centers for Medicare & Medicaid Services Quality Measure Report Appendix" (2021).

¹⁴NIDDK. "Anemia in Chronic Kidney Disease." <https://www.niddk.nih.gov/health-information/kidney-disease/anemia#complications> (accessed June 22, 2021).

¹⁵*Supra* note 12 at Chap. 2. See Figure 2.1d, by Race.

¹⁶*Id.*

dialysis were administered ESA each month during 2018, compared with 52 percent of White patients.¹⁷ However, irrespective of modality, the mean hemoglobin values among patients treated with an ESA were lower for Blacks than Whites, 10.33 compared to 10.43 mg/dL, respectively, in hemodialysis patients and 10.13 versus 10.32 mg/dL in peritoneal dialysis patients. (USRDS Figure 5 by race).

These data points demonstrate that a measure focused on better management of anemia in the dialysis facility will more likely lead to improved patient outcomes than a measure directed at transfusions, which are one or more steps removed from the dialysis setting. Doing so could help improve the outcomes of Black patients.

Standardized Hospitalization Ratio (SHR) and Standardized Readmission Ratio (SRR). The QIP should use true risk-standardized rate measures, as the ratio measures have relatively wide confidence intervals that can lead to facilities being misclassified and their actual performance not being reported. Both hospitalization and readmissions rates have increased between 2016 and 2018, indicating the QIP has had no impact—or perhaps even a perverse impact—on these aspects of care. For the SHR, the 2021 CMS Impact Assessment shows an increase in the mean observed-to-expected ratio, with a score of 182.2 in 2016 that increased to 188.5 in 2018 (lower scores are better).¹⁸ The SRR has performed similarly. The 2021 CMS Impact Assessment found that the average proportion (observed-to-expected) across dialysis facilities increased from 26.3 in 2015 to only 27.8 in 2018.¹⁹

A hospitalization measure is critically important for driving quality improvement for individuals receiving dialysis and for informed patient decision-making. KCP believes a more direct, transparent, risk-adjusted rate measure as part of a smaller set of measures would result in more significant improvement year over year. CMS could use the underlying hospitalization and readmission rates and appropriately risk adjust them using race and ethnicity, as is done with the Standardized Mortality Ratio (SMR). We recommend that the agency build off of its prior contracted work with NQF and develop socio-demographic adjusters and submit the new measures to NQF for endorsement consideration.

Given the burden that hospitalizations and readmissions have on patients, having a metric that accurately represents the performance of facilities is critically important to empowering patients. In 2018, the adjusted rates of overall hospitalizations among Medicare ESRD beneficiaries were fairly high among all patients:

- White: 1,771 hospitalizations per 1,000 patients
- Black/African American: 1,758 hospitalizations per 1,000 patients

¹⁷*Id.*

¹⁸*Supra* note 13.

¹⁹*Id.*

- American Indian/Native Alaska Native: 1,572 hospitalizations per 1,000 patients
- Asian: 1,183 hospitalizations per 1,000
- Native Hawaiian/Pacific Islander: 1,512 hospitalizations per 1,000 patients²⁰

When compared with the general Medicare population, these rates are extremely high. One study looking at 2016 data found that there were 243.2 hospitalizations per 1,000 patients in traditional Medicare and 185.4 hospitalizations per 1,000 patients in Medicare Advantage plans.²¹ The Kaiser Family Foundation reports there were 240 hospitalizations per 1,000 Medicare beneficiaries in 2018.²² Clearly, hospitalizations and the related readmissions rates are areas where there could be substantial improvement for all patients, but especially patients from communities of color.

In addition to not accurately reflecting facility performance because of the use of a ratio rather than a rate and the lack of being risk adjusted, the SHR and SRR measures are not reliable, with overall inter-unit reliability (IUR) of 0.35 and 0.55, respectively. (Statistical literature traditionally interprets a reliability statistic of 0.50-0.60 as “poor.”²³) Importantly, reliability statistics were not stratified by facility size when the measures were submitted to NQF for endorsement maintenance.

Prior trends reported by CMS indicate that smaller facilities will likely have IURs significantly lower than the global statistics presented above, such that the scores received by smaller facilities can be expected to be largely attributable to random noise and not signal. Such facilities, many of which treat small rural or low-income communities, will be disproportionately impacted, resulting in random and specious penalties being imposed on the most financially vulnerable facilities treating the most socially and medically disadvantaged patients.

Moreover, patients residing in such areas, already shouldering significant social risk-related disparities, cannot trust the measures as a valid representation of performance to help inform their decision-making. Ensuring that performance measures addressing these critical clinical topics provide reliable information is vital to improving outcomes and necessary to reducing facility and patient burden and confusion; it is incumbent on CMS to demonstrate reliability for all facilities by providing data by facility size.

²⁰*Supra* note 12 at ESRD Ref. G. Hospitalizations G.2.1.

²¹ Robert Graham Center. “Understanding the Impact of Medicare Advantage on Hospitalization Rates.” (2016) https://www.graham-center.org/content/dam/rgc/documents/publications-reports/reports/BMA_Report_2016.pdf (accessed June 22, 2021).

²²Kaiser Family Foundation. “Medicare Service Use: Hospital Inpatient Services.” (2021) <https://www.kff.org/medicare/state-indicator/medicare-service-use-hospital-inpatient-services/?currentTimeframe=1&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (accessed June 22, 2021).

²³ Adams JL. *The Reliability of Provider Profiling: A Tutorial*. Santa Monica, California:RAND Corporation. TR-653-NCQA, 2009.

Percentage of Prevalent Patients Waitlisted (PPPW). KCP remains concerned about the use of the PPPW in the ESRD QIP. The NQF has formally rejected this measure, concluding that it lacks validity. Lacking validity means that the PPPW measure does not provide an accurate assessment of facility performance. The first year for which CMS has reported scoring information (2018) in the 2021 CMS Impact Assessment shows a relatively low score of 19.2, when larger results indicate better performance.²⁴ Part of the problem is that the measure fails to measure actions taken by dialysis facilities. “Fair and accurate attribution is essential to the success of value-based purchasing and alternative payment models.”²⁵ If patients or other stakeholders were to use it to make medical decisions, they would be using invalid information.

An invalid measure will only perpetuate the substantial health disparity that exists when it comes to accessing transplants. The disparities in wait-listing are pervasive and well-documented:

- Black patients are less likely to receive a preemptive kidney transplant (20.9 percent) than White patients (33.2 percent).
- Among patients who were initially wait-listed in 2013, median wait-time was 5 years for Black patients but only 3.4 for years for White patients, a difference of more than 1.5 years.
- The number of White patients on the waiting list with active status increased 0.5 percent between 2017 and 2018, compared to a 1.0 percent decrease in Black patients.
- In 2018, the prevalence of preemptive wait-listing was 5.0 percent among White patients and 3.9 percent among Blacks, and one-year cumulative incidence of wait-listing or transplantation was 13.7 percent in White patients and 10.3 percent in Black patients.
- The pattern of racial disparities also differs markedly by source of transplant; rates of deceased donor transplantation among Black and White patients have been equivalent over the past 3-4 years, whereas a large disparity in living donor transplant rate remains and accounts for the difference in overall transplantation rates between Black and White individuals in 2018.²⁶

Transplant centers assess a myriad of demographic factors—*e.g.*, family support, ability to adhere to medication regimens, capacity for follow-up, insurance-related issues, among others. Use of these types of sociodemographic factors only reinforces that those who face sociodemographic barriers when it comes to health care generally will now also experience them when it comes to trying to access a kidney or other organ transplant.

²⁴*Supra* note 13.

²⁵NQF, “NQF Report of 2018 Activities to Congress and the Secretary of the Department of Health and Human Services” 13 (March 1, 2019).

²⁶*Supra* note 12 at Chap. 6.

Recognizing the importance of developing a measure that is actionable and reflects the work dialysis facilities undertake to help patients be added to waitlists, KCP through the Kidney Care Quality Alliance (KCQA) is convening a group of transplant and kidney care experts to develop a measure that will be submitted to NQF for consideration. We encourage CMS to work with the community in this process. Until a valid measure is developed, we ask that CMS not perpetuate the inequities in the transplant system by using a measure that will penalize facilities treating the patients most in need of resources to address their health needs.

Standardized Fistula Rate and Long-Term Catheter Rate. KCP supports measures focusing on the reduction of catheters and increasing the number of patients with an AV Fistula, when appropriate for the patient. However, to reduce the measure set to address concerns raised by recent peer-reviewed articles, emphasizing the long-term catheter rate in the ESRD QIP would achieve the common goal of reducing catheters in favor of grafts and fistulas. As such, CMS should consider moving the fistula measure to Facility Compare and adjusting or stratifying the catheter for age, race and ethnicity, and insurance status prior to dialysis initiation.

CMS adopted new catheter and AV fistula measure for PY 2018 and only one year of data are available in the 2021 CMS Impact Assessment for this measure.²⁷ However, a recent publication assessing the impact of the QIP on vascular access provides additional data that indicate performance has not improved under the program:²⁸ Mean AVF rates of the 4804 included facilities initially increased from 63.7 percent in PY 2014 to 67.2 percent in PY 2016 ($p < 0.05$). However, rates did not change in PY 2017 and then declined significantly to 64.1 percent in PY 2020, which is near AVF rates at the inception of program. Likewise, for those 4804 facilities, LTC rates decreased from 10.4 percent in PY 2014 to 9.88 percent in PY 2015 ($p < 0.05$), but then increased again between to rates higher than at the inception of program, at 11.8 percent in PY 2020 ($p < 0.05$). Facilities serving majority Black ZIP Code Tabulation Areas (ZCTAs) or ZCTAs with median income <\$45,000 achieved significantly lower AVF rates ($p < 0.05$) with no significant difference in LTC rates ($p > 0.05$).

Vascular access discrepancies have been consistent for both incident and prevalent over the past decade. Most recently:

- In 2018, highest catheter use at hemodialysis initiation was observed in adults aged 18-44 years (86.5 percent versus 63-65 percent in other age groups), patients of Hispanic or Latino ethnicity (84.7 percent versus 80.0 percent), and those with dual eligibility for Medicare and Medicaid (85.7 percent versus 79.5 percent in patients with Medicare as a secondary payer, for instance).

²⁷Supra note 13.

²⁸ Shah S et al. CMS ESRD Quality Incentive Program has not improved patient vascular access. *J Vasc Access*. 2021 Jul 5. PMID: 34219530, DOI: [10.1177/11297298211027054](https://doi.org/10.1177/11297298211027054).

- In prevalent patients that same year, catheter use was much higher in women than men (19.9 percent versus 15.8 percent), in Whites (18.3 percent versus 14-17 percent in other race groups). Distribution of vascular access was similar among those with Medicare fee-for-service and those in Medicare Advantage plans.²⁹

Stratifying the quality measures will allow health care providers and other stakeholders to identify and prioritize differences in care, outcomes, and experiences across the different racial and ethnic groups. They will be able to develop and implement equity-focused practices to address disparities and better understand the experiences of patients from communities of color.³⁰ Thus, we also encourage CMS to stratify these measures to help address the clear gaps that exist in the area of vascular and home dialysis access placements.

Patient Experience Measure. In the ESRD QIP and Five Star programs, the In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (CAHPS) serves as the patient satisfaction metric. KCP believes it is important to include the ICH CAHPS in the ESRD quality programs, but the fielding of the current measure has created such a high level of patient burn-out with completing the lengthy survey twice a year that the measure is no longer valid. CMS's own data show that response rates are low and continue to drop, threatening the validity of ICH-CAHPS as an accountability measure. Response rates are currently approximately 35 percent, raising concern for possible underrepresentation of patient groups. For instance, in a cross-sectional analysis of survey administration to 11,055 eligible in-center hemodialysis patients across the U.S., Dad et al.³¹ reported in 2018 that non-responders (6,541 [59 percent]) significantly differed from responders, broadly spanning individuals with fewer socioeconomic advantages and greater illness burden, raising limitations in interpreting facility survey results. Non-responders were more likely to be men, non-white, younger, single, dual Medicare/Medicaid eligible, less educated, non-English speaking, and not active on the transplant list.

Based on the analyses above, it is no surprise that the average annual percentage of change (AAPC) in the performance measured by the ICH CAHPS is extremely low. The ratings are divided in the following categories:³²

²⁹*Supra*, note 12 at Chap. 3.

³⁰See Advancing Health Equity. "Using Data to Reduce Disparities and Improve Quality." <https://www.solvingdisparities.org/sites/default/files/Using%20Data%20Strategy%20Overview%20Oct.%202020.pdf> (accessed June 22, 2021).

³¹Dad T et al. Evaluation of non-response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey. *BMC Health Services Research*. 2018;18:790.

³²*Supra* note 13.

| | Dialysis center staff | Dialysis facility | Nephrologist | Nephrologists' communications and caring | Information provided to patients | Dialysis center care and operations. |
|------|-----------------------|-------------------|--------------|--|----------------------------------|--------------------------------------|
| AAPC | 1.0 | 0.9 | 0.6 | 0.6 | 0.3 | 0.7 |

Understanding the patient’s perspective and incorporating it into health care decision-making is critical. Rather than being a barrier to the Administration’s goal of achieving that outcome, ICH-CAHPS should be administered to patients once a year (not twice) to reduce burdens on patients. When asking patients to complete the survey, the contractor should divide the survey into the three validated section and field each one. CMS recognizes that the survey can be separated into different sections for analysis in the 2021 CMS Impact Assessment of the ICH CAHPS measures. That document reports performance in six sections: dialysis center staff, dialysis facility, nephrologist, nephrologists’ communications and caring, information provided to patients, and dialysis center care and operations.³³ Then, while a facility would be surveyed on the complete tool, any one patient would have to complete only one-third of the questions. CMS should exclude the homeless to whom the survey cannot be distributed, given that facilities are not allowed to provide the survey directly to patients.

In addition, we reiterate our outstanding request that the survey be revised to include home dialysis patients and that CMS obtain NQF endorsement of the new measure, which MedPAC and others in the community also have consistently requested. An alternative to this approach would be to adopt a home dialysis specific metric. We appreciate that CMS has completed some work on modifying the current tool, but given the Administration’s strong desire to incentivize home dialysis, having an in-center only tool seems to contradict that position.

Finally, it is important that CMS allow facilities and patients to use the ICH-CAHPS survey results to improve care. Patients and physicians participating in the previous TEP on patient-outcomes measures raised concerns multiple times that the fact that facilities never see the results and cannot communicate with patients about the results leaves patients feeling as if they had wasted their time completing the survey. Patients want to be heard. As currently administered, ICH-CAHPS has the opposite effect. Given that the majority of dialysis patients are from communities of color, the administration of the ICH-CAHPS survey does them a great disservice by further marginalizing their voices.

Kt/V Comprehensive Clinical Measure and Ultrafiltration Measure. To promote transparency in dialysis performance, KCP recommends that CMS use the distinct adult hemodialysis and peritoneal dialysis adequacy adult and pediatric measures endorsed by the NQF. NQF decided not to endorse this comprehensive measure. A pooled measure approach results in all patients from the four dialysis populations (adult and pediatric, peritoneal and hemodialysis) being combined into a single denominator and scores being

³³*Id.*

calculated as would be done for a single measure. While the vast majority of patients do receive adequate dialysis (urea clearance),³⁴ this pooled approach to reporting eliminates the ability to determine performance on any specific patient population or dialysis modality and perhaps masks social disparities in this aspect of care. Patients need to understand a facility's actual performance on the different modality types to make informed decisions about modality choice; the pooled measure hides this information from patients.

In addition, the 2021 CMS Impact Assessment finds only a 0.7 percent average annual improvement on the measure during the last three years.³⁵ This is likely because the metric is topped out. While KCP supports its continued use in the QIP, acknowledging that the statute requires its use as well, the value of including it rests in distinguishing in-center and home dialysis performance, which the pooled measure does not permit.

As the measure developer for the NQF-endorsed Ultrafiltration Measure (UFR), KCP supports its use in the ESRD QIP. To the extent the Congress modifies the authorizing statute, as has been proposed in S. 1971/H.R. 4065, "Chronic Kidney Disease Improvement in Research and Treatment Act," the topped out Kt/V measure could be eliminated. The UFR measure would be a more appropriate metric for evaluating patient outcomes. We appreciate CMS adopting the KCP specification of patient-months, which the KCQA adopted so the measure was more patient-centered. While there is still only one year of reporting data for this measure, the average score was 97.6 percent, indicating the measure is feasible and can be converted to a clinical measure when CMS is ready.³⁶

NHSN Bloodstream Infection in Hemodialysis Patients Clinical Measure and NHSN Reporting Measure. KCP remains deeply concerned about the reliability and validity of the BSI measure. CMS is not using the measure adopted by NQF in the QIP, but a modified version. Research conducted by the CDC (the measure developer) and others, including CMS, show that the measure is not a valid representation of the care provided. CMS data shows that as many as 60-80 percent of dialysis events may be under-reported with the NHSN BSI measure.³⁷ In a follow-up TEP, CMS and other HHS agency officials indicated that the percentage was slightly lower, but TEP members remained concerned that the percentage is still unacceptably high. The measure in many instances may incorrectly report that a facility has a low number of blood stream infections when the opposite may in fact be true.

The 2021 CMS Impact Assessment validates this concern. During 2015, 2016, 2017, and 2018, the average observed-to-expected ratios for the measure were 0.9, 0.9, 0.8, and

³⁴*Supra* note 12.

³⁵*Supra* note 13.

³⁶*Id.*

³⁷81 *Fed. Reg.* 77834, 77879.

0.7 respectively.³⁸ Knowing the underlying problems with the data, this might suggest an increase in under-reporting rather than quality improvement.

Given the understandable importance that patients place on a facility's ability to manage blood stream infections, a measure that fails to accurately represent the facility's performance deprives patients of their ability to make informed healthcare decisions and may obscure social disparities. It also unfairly penalizes facilities that diligently pursue and report the hospital infection data necessary for a full picture of infection rates. Simply put, the measure is not reporting accurate data to patients or providers. Knowing the importance of this measure, KCP through the KCQA plans to develop a BSI measure to replace the flawed one in the ESRD QIP. We encourage CMS to avoid misinforming patients. One way to address this problem in the short term is for CMS to provide dialysis facilities with the patient-level BSI data from hospital claims to which facilities do not have direct access. These data points would be most easily provided to facilities via EQRS or another existing system. Otherwise, CMS should suspend the use of this NHSN BSI measure and rely upon the NHSN Dialysis Event Reporting Measure until a valid and reliable measure is available, which could be as soon as the next rulemaking cycle.

Until a valid and reliable BSI measure can be added to the QIP, KCP continues to support the NHSN Dialysis Event measure as a reporting measure. We reiterate our request that CMS submit this measure for NQF review, consistent with the statutory language indicating that CMS should use measures endorsed by the body selected to review them, which in this case is the NQF. Additionally, we renew our recommendation that the addition of a set of subjective factors (*e.g.*, redness, swelling) to the measure be eliminated because these factors do not support the purpose of the measure.

Hypercalcemia Measure. CMS should retire the Hypercalcemia Measure from use in the ESRD QIP. It is based on NQF #1454, which the NQF has placed in reserve status because the measure has "topped-out" (*i.e.*, there is little room for additional improvement in this clinical area) and provides no significant benefit for patients. Therefore, CMS should remove the measure from the QIP.

Clinical Depression and Screening. While monitoring for clinical depression is important, KCP believes 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 patients and care partners with information about how individual facilities perform in terms of screening for clinical depression, CMS could include it in the Facility Compare program instead. The measure also appears to be topped out with the proportion of patients being screened in 2016, 2017, and 2018 equaling 96.8 percent, 98.6 percent, and 98.8 percent respectively.³⁹

³⁸*Supra* note 23.

³⁹*Id.*

B. KCP reiterates its concerns about the proposed updates to the SHR Measure.

KCP supports CMS's decision to align measures in the ESRD QIP with the specifications endorsed by the NQF. However, as we noted in our comments to the MAP, we have concerns about the modifications to the SHR measure.

First, CMS modified the risk adjustment method to include a prevalent comorbidity adjustment, the addition of Medicare Advantage (MA) enrollees, and an MA indicator in the model. KCP recommended that CMS perform a sensitivity analysis of risk model fit under the previous approach and the new in-patient-claims-only approach. Without such an analysis, it is not possible to assess with the information provided whether model fit improved or worsened with the new approach. Given the importance of this measure for patients and providers, we ask that CMS provide this analysis to stakeholders to create greater transparency around the measure.

With regard to the prevalent comorbidity adjustment, CMS indicated that for the SHR it would limit the data used for the adjustment to inpatient claims. KCP is concerned that limiting comorbidity data to inpatient claims might skew models towards a sicker population. This means that the model will necessarily underestimate the comorbidity profile of patients in facilities with low hospitalization rates. The "expected" hospitalization rates calculated for such facilities would be erroneously low, and the facilities scores would be erroneously high. This skewing could result in facilities that successfully keep hospitalization rates low being scored unfavorably on the measure, misleading patients and disincentivizing providers behaviors that actually lower hospitalizations.

Second, CMS updated the parameterization of existing adjustment factors and re-evaluation of interactions. KCP agrees that this update is important. However, as we shared with the Measures Application Partnership (MAP) many of the prevalent comorbidities in the final SHR risk model had p-values significantly greater than 0.05. We remain concerned that these p-values indicate a model that will not be generalizable. In the current model, for example, asthma is associated with a higher risk of hospitalization than critical illness myopathy, and "complete AV block" is protective while "mood disorders" are harmful. We believe that these inexplicable findings are a function of collinearity and coding idiosyncrasy. KCP supports prevalent comorbidity adjustment, but we are concerned that the proposed collection of adjusters will be less robust with each year that passes from initial model development.

Before CMS finalizes these modifications in the ESRD QIP, we ask that the agency (1) provide the sensitivity analysis and (2) address the skewing concerns as well as the inexplicable findings related to the parameterization modifications.

C. KCP supports the proposal to use CY 2019 as the data for calculating the performance standards, achievement thresholds, and benchmarks for PY 2024.

KCP appreciates that CMS heard the community's concerns about using CY 2020 data for future performance standards, achievement thresholds, and benchmarks due to the pandemic. We strongly support the proposal to calculate these standards, thresholds, and benchmarks for PY 2024 using CY 2019 data, which is the most recently available full calendar year of data available. We also agree with the statutory authority CMS describes that allows for this substitution of the performance standard, achievement thresholds, and benchmarks.

D. KCP renews our request for CMS to address the problem that the measures produce random results when applied to facilities with fewer than 25 patients, preventing the QIP from driving quality improvement in those facilities and misleading patients.

KCP reiterates our request that CMS address the problem of small numbers. The decision to include facilities with 11 or more cases as the basis for measure applicability instead of the more widely accepted 25 or more cases that commercial insurers and other private quality programs typically apply undermines the statistical reliability of the measure results. We appreciate the work CMS has done on the small facility adjuster, but as KCP analyses have repeatedly shown, the current policy unfortunately does not eliminate the random results associated with small numbers. We encourage CMS to review the work that the NQF has completed in relation to rural areas that identifies ways to develop measures that can be used without small numbers negatively impacting the outcomes reported, as well.

E. KCP supports the proposed payment reduction scale for the PY 2024.

KCP supports maintaining the current policies and methodologies underlying to payment reduction to allow for year-over-year comparison of QIP results.

IV. With the caveats noted for PY 2024, KCP supports the proposed updates for the PY 2025.

As we have indicated in previous comment letters, we appreciate that CMS recognizes the importance of maintaining the structural aspects of the ESRD QIP year-to-year that allow for multi-year comparisons of providers. This consistency is appropriate and helpful. Thus, KCP supports the proposals for PY 2025 that maintain the performance period, performance standards, and scoring aspects of the program. Consistent with our comments about PY 2024, we continue to urge CMS to reduce the number of measures in the ESRD QIP to prioritize those with greater impact on patient outcomes.

V. KCP requests that CMS align the ESRD quality programs to reduce confusion and inconsistencies in the measures and their incentives.

Consistent with the CMS Action Plan, KCP would like to reiterate our commitment to work with CMS to eliminate the inconsistencies and conflicts that have arisen among the various Medicare ESRD quality programs. In previous comment letters, KCP has suggested a way to align the programs, both in terms of measures and structural scoring issues. We ask again that CMS review these recommendations and work with KCP to strengthen both programs to Facility Compare (FC and previously known as Dialysis Facility Compare) and the QIP to achieve the independent goals CMS has identified for each and that would preserve the Congressional intent for the ESRD QIP.

The chart below outlines the suggestions of the members of KCP for focusing FC on meaningful measures that are not used in the ESRD QIP and providing patients with the data about each measure on its website in a way that allows patients to prioritize the measure results they want to see. The ESRD QIP would be a smaller set of meaningful measures that ensure that each measure has substantial weight to avoid any one measure being diluted by the others. Because the Congress mandated that the QIP be a public reporting program, we suggested that CMS shift the star ratings to the QIP TPS scores.

KCP Recommendations for Distributing Measures Across the QIP and FC

| | |
|--------------------------|-------------------------|
| ESRD QIP Measures | ESRD FC Measures |
|--------------------------|-------------------------|

| | |
|--|---|
| Standardized hospitalization rate measure (current ratio measure modified to a true risk-standardized rate) | KCQA UFR Measure |
| Standardized readmissions rate measure (current ratio measure modified to a true risk-standardized rate) | KCQA Medication Reconciliation (MedRec) Measure |
| Catheter > 90 Days Clinical Measure | NHSN Healthcare Personnel Influenza Vaccination Reporting Measure |
| Bloodstream infection measure (not the current measures, but one that is valid and reliable and meets other NQF criteria) | Kt/V Dialysis Adequacy Comprehensive Clinical Measure (modified to return to individual dialysis adequacy measures) |
| Patient Experience of Care: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Clinical Measure (modified per historic recommendations) | Standardized AV Fistula measure |
| Hgb < 10 g/dL | Clinical Depression Screening and Follow-Up Reporting Measure |

| ESRD QIP Measures | ESRD FC Measures |
|--|---|
| Serum phosphorous | Standardized Mortality Rate measure (current ratio measure modified to a true risk-standardized rate) |
| Transplant referral measure, including assistance with first visit | Patient Reported Outcome Measure (when developed and endorsed) |

We also would ask that each of these measures be refined based on KCP recommendations for the specific measures. We have also suggested that CMS could align the two programs by ensuring that the DFC and QIP measures have the same specifications and the same scoring mechanism.

We encourage CMS to carefully review these proposals and would welcome the opportunity to identify ways of better aligning the ESRD QIP and DFC so that patients could use both programs for decision-making, but each one would be supportive of the other rather than conflicting as they are today.

VI. KCP appreciates the opportunity to provide comments on the requests for information (RFI) topics outlined in the Proposed Rule.

Patients with kidney disease are disproportionately from communities of color and experience inequities in the delivery of health care. Disparity in the incidence of ESRD between Blacks and Whites is striking, and progress in closing this gap has been slow. According to the USRDS 2020 Annual Data Report,⁴⁰ the adjusted prevalence of ESRD was 3.4 times higher in Blacks than Whites in 2018. ([USRDS Figure 1.8](#) by race). Ten years earlier, that ratio was 3.8, highlighting the slow progress in addressing the disparity in ESRD prevalence.

Likewise, ESRD prevalence in Hispanic populations was found to be more than 1.5 times higher than in non-Hispanics in 2018. ([USRDS Figure 1.8](#) by ethnicity). Additionally, Black, Asian, Native Hawaiian or Pacific Islander, and multiracial populations were more likely to be diagnosed later in the disease process. For example, compared to 58 percent of White patients, 74 percent of Blacks were diagnosed with ESRD at an eGFR of less than 10 mL/min/1.73 m². ([USRDS Figure 1.20](#) by race and by ethnicity).

Black and Hispanic patients also frequently experience barriers to receiving a transplant or being able to select home modalities.⁴¹ Black patients are less likely to initiate peritoneal dialysis (5.9 percent) or receive a preemptive kidney transplant (20.9

⁴⁰ United States Renal Data System. [2020 USRDS Annual Data Report](#). Epidemiology of kidney disease in the United States. Chap. 1. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.

⁴¹*Id.* at Chap. 6.

percent) than White patients (8.1 percent and 33.2 percent, respectively). Among patients who were initially wait-listed in 2013, median wait-time was 5 years for Black patients but only 3.4 for years for White patients, a difference of more than 1.5 years. ([USRDS Figure 6.9](#) by race). Between 2017 and 2018, the number of Black patients on the waiting list for a kidney transplant decreased 4.7 percent, compared to only a 1.2 percent decrease in White patients. The number of White patients on the waiting list with active status increased 0.5 percent between 2017 and 2018, compared to a 1.0 percent decrease in Black patients. In 2018, the prevalence of preemptive wait-listing was 5.0 percent among White patients and 3.9 percent among Blacks, and one-year cumulative incidence of wait-listing or transplantation was 13.7 percent in White patients and 10.3 percent in Black patients. The pattern of racial disparities also differs markedly by source of transplant; rates of deceased donor transplantation among Black and White patients have been equivalent during the past 3-4 years, whereas a large disparity in the living donor transplant rate remains and accounts for the difference in overall transplantation rates between Black and White individuals in 2018. Hispanic or Latino patients were also less likely to receive a preemptive transplant (1.75 percent) than non-Hispanic patients (2.56 percent).⁴²

Dialysis patients are often poorer and sicker than other Medicare beneficiaries and rely on federal and state subsidizes and welfare programs, such as Medicaid. In 2018, ESRD beneficiaries made up about 1 percent of total Medicare enrollment and 2.5 percent of dual-eligible enrollment.⁴³ The dual-eligible population may also have different social risks, with associated implications for health outcomes and service use. Dually eligible beneficiaries with ESRD are more often people of color and have higher costs compared to non-duals, despite similar utilization patterns to their non-dual-eligible counterparts.⁴⁴ The systemic barriers to accessing basic healthcare likely play a substantial role in these individuals developing kidney disease and progressing to kidney failure; for example, Medicare–Medicaid dual eligibility status has been found to correlate with a lower likelihood of pre-ESRD nephrology care.⁴⁵

The systemic barriers to accessing basic health care likely play a substantial role in these individuals developing kidney disease and progressing to kidney failure. The leading causes of CKD and ESRD are hypertension, diabetes, and obesity. Black and Hispanic individuals are diagnosed with these diseases more than other Americans.⁴⁶ We know from several years of research that people of color have more difficulties accessing

⁴²*Id.*

⁴³Avalere. [Comparison on Dually and Non-Dually Eligible Patients with ESRD](#). July 9, 2020.

⁴⁴Avalere. [Comparison on Dually and Non-Dually Eligible Patients with ESRD](#). July 9, 2020.

⁴⁵Nee R et al. Impact of poverty and race on pre-end-stage renal disease care among dialysis patients in the United States. *Clin Kidney J.* 2017;10(1):55-61.

⁴⁶Richard V. Reeves & Faith Smith. “Up Front: Black and Hispanic Americans at Higher Risk of Hypertension, Diabetes, and Obesity: Time to Fix Our Broken Food System.” *Brookings*. <https://www.brookings.edu/blog/up-front/2020/08/07/black-and-hispanic-americans-at-higher-risk-of-hypertension-diabetes-obesity-time-to-fix-our-broken-food-system/> Aug. 7, 2020). accessed June 28, 2021.

preventative care and chronic disease management services.⁴⁷ It is very likely that the challenges these individuals faced when trying to access basic health care services resulted in their diseases not being fully managed, which led to the development of kidney disease.

There are very limited comprehensive disease management programs for individuals at-risk of developing kidney disease. Other than six educational sessions for a small number of existing Medicare beneficiaries, Medicare does not offer benefits specific to CKD to help patients manage and slow the progression of their disease.⁴⁸ The program that does exist is not widely utilized.

The KDE education benefit is one way to help patients prepare for dialysis by sharing their options. However, the program should be expanded to allow patients to access it earlier in the disease state and to allow more providers to be able to provide their services. Legislation introduced in the Senate and soon to be in the House would: (1) allow dialysis facilities to provide kidney disease education services; (2) permit physician assistants, nurse practitioners, and clinical nurse specialists, in addition to physicians, to serve as referral sources for the benefit; and (3) to provide access to these services to Medicare beneficiaries with Stage V CKD not yet on dialysis.

Such programs can be rare in commercial insurance as well. Because Medicare provides a safety net of coverage for ESRD patients, many commercial plans include provisions in their plan designs that essentially push their enrollees into Medicare before the individuals are legally required to give up their commercial coverage. KCP and its members have documented multiple examples of this type of behavior and raised concerns about the ongoing practice for the last several years. Given that these plans can avoid the cost of dialysis and/or transplant, they have little to no incentive to spend resources and time trying to prevent the progression of kidney disease to kidney failure.

Another early patient decision points in Stage III or IV can be modality selection. During the last several years, KCP has sought to work with the federal government to remove barriers that make it more difficult for patients who want to select home dialysis to do so. Thus, KCP is pleased that the Administration has prioritized encouraging more Medicare beneficiaries who require dialysis to select home dialysis modalities. As the GAO has noted, there are many reasons that patients may not select these modalities, most of which center around socio-economic issues. However, we recognize that there are steps the federal government can take to help expand education and incentives. With this goal in mind, we encourage CMS to adopt the following policies:

⁴⁷Kenneth E. Thorpe, Kathy Ko Chin, Yarira Cruz, *et al.* "The United States Can Reduce Socioeconomic Disparities by Focusing on Chronic Diseases." *Health Affairs* (Aug. 17, 2017) <https://www.healthaffairs.org/doi/10.1377/hblog20170817.061561/full/>. accessed June 20, 2021.

⁴⁸As discussed below, Medicare through its demonstration programs has tested and plans to test additional health care delivery models to better manage CKD. To date, none of these programs has resulted in changes to the fee-for-service benefit in which the vast majority (xx%) of ESRD patients are enrolled.

- Expand the Medicare Kidney Disease Education program, as noted above, to: (1) allow dialysis facilities to provide kidney disease education services under certain circumstances; (2) permit physician assistants, nurse practitioners, and clinical nurse specialists, in addition to physicians, to serve as referral sources for the benefit; and (3) to provide access to these services to Medicare beneficiaries with Stage 5 Chronic Kidney Disease (CKD) not yet on dialysis.
- Remove fraud and abuse barriers by allowing ESRD facilities to provide education of CKD patients;
- Support collaboration among providers by waiving fraud and abuse restrictions so that:
 - Health care providers are allowed to share population health tools and predictive modeling technology to support practitioners with management of CKD patients and transplant progression; and
 - Licensed health care professionals should be allowed to provide education on all modalities to a hospitalized patient with kidney failure at the request of the patient’s care team, including discussion of in-center and home dialysis modalities, management of kidney failure without dialysis, and kidney transplantation. The decision regarding modality choice should be the result of a shared decision-making process between the patient and the nephrologist.
- 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.

Additionally, we encourage OMB to work with the community to support funding for screening individuals for kidney disease on regular basis. There are treatment options and steps individuals with the disease can take to slow its progression, but they must be aware of the condition first. Along these lines, KCP also supports legislation introduced in the Senate that would add kidney disease screening to the Welcome to Medicare visit.⁴⁹

As an organization that represents patients, physicians, nurses, other health care professionals, manufacturers, and dialysis facilities from more than 30 different kidney care organizations throughout America, we have focused on helping the federal government maintain its strong and unique commitment to Americans living with kidney disease. As the Administration continues to seek ways to address health disparities, we

⁴⁹S. 1971, “Chronic Kidney Disease Improvement in Research and Treatment Act.”

encourage CMS to work with KCP on the recommendations identified in this letter to align the payment system with this goal.

A. KCP supports addressing health equity gaps in the quality programs through appropriate risk adjusters and/or stratification when appropriate.

In Section 3 of this letter, KCP outlines suggestions about social risk considerations for the specific measures in the QIP and summarizes those comments once again in this section. Generally speaking, we agree that some measures in the ESRD quality programs should be adjusted to advance health equity. In some instances, it may be more appropriate to establish risk adjusters, but we also recognize that stratification can be an appropriate solution, especially as more data are gathered to establish appropriate risk adjusters.

While not perfect, we recognize that dual eligibility status appears to be an appropriate initial proxy for addressing socioeconomic status, including race and ethnicity. It is important that the data used be 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. 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 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. We recommend the CMS establish an open and transparent process as it reviews the responses to this RFI and works with NQF and other organizations to allow for an ongoing community dialogue as it develops data options as well. We also ask that the risk adjusters and the methodologies rely upon data elements available to providers and that the calculation can be replicated to promote transparency.

1. KCP recommends that certain measures be evaluated for stratification or risk adjustments.

Consistent with our comments in Section 3 and comments from the 2018 rulemaking process, KCP recommends that the following measures should be assessed for establishing socio-demographic status (SDS) stratification or risk factor adjustments.

- Standardized Readmission Ratio (SRR)
- Standardized Transfusion Ratio (STrR)
- Standardized Mortality Ratio (SMR)

- Standardized Hospitalization Ratio (SHR)

While the SMR is already adjusted for race/ethnicity, the other standardized ratio measures are not. SDS factors should also be considered, even as we encourage CMS to shift these measures from ratios to rates. Whether the measure is expressed as a rate or ratio is immaterial to evaluating the need for SDS factors. In other settings, there is a wide and increasingly deep evidence base that performance on these measures is driven in part by patient-level SDS factors. Similar trends appear to be occurring in the context of readmission measures in other health care settings as well. There is no reason to believe that the ESRD population is any different.

We believe CMS should examine whether insurance status at the time of dialysis initiation should be applied to the following measures:

- Vascular Access Type (VAT) Measure Topic – Arteriovenous Fistula (AVF) Clinical Measure
- Vascular Access Type (VAT) Measure Topic – Catheter > 90 Days Clinical Measure

Patients initiating dialysis without insurance likely have difficulties in securing appropriate pre-dialysis care by a nephrologist, including referral and placement of, and payment coverage for, permanent access. We recognize some allowance has been made (e.g., the catheter measure is three consecutive months) to assess this concern, but believe additional review of an insurance coverage risk variable is warranted given the time that often elapses for appointment availability, placement, and maturation of permanent access.

We do not believe SDS factors should be applied to the following measures:

- Kt/V Dialysis Adequacy Comprehensive Clinical Measure
- Hypercalcemia Clinical Measure
- Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) Measure (NQF #2988)

Based on the experience of KCP members, as well as other research, there is no evidence suggesting that performance on these measures is so influenced by SDS factors that they should be adjusted to ensure that the information they provide accurately reflects the true performance of each facility.

Similarly, while we remain deeply concerned about the validity of the National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Patients Clinical Measure, we also do not think that this measure should be adjusted for SDS factors.

We also do not believe that reporting measures need to be adjusted for SDS factors because the focus is on whether the facility has reported the necessary data and not patient outcomes.

It is less clear as to whether SDS factors affect the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Clinical Measure scores. While this measure continues to be problematic because of the administration parameters that result in substantial patient fatigue in completing it, which has led to a declining response rate, it is simply not clear what impact SDS factors might have on the patients who responds to the survey. Therefore, we believe the Agency should review and make publicly available the data required to evaluate the impact of SDS factors.

Finally, as CMS should evaluate the SDS factors that clearly impact transplant referrals and patient placement on organ waitlists. Geography, for instance, should be examined, since regional variation in transplantation access is significant. For example, regional differences in waitlist times differ, which ultimately will change the percentage of patients on the waitlist and impact a performance measure score. That is, facilities in a region with long wait times will “look” better than those in a region with shorter wait times where patients come off the list more rapidly—even if both are referring at the same rate. Additionally, criteria indicating a patient is “not eligible” for transplantation can differ by location—one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while another may apply them differently or have additional/different criteria. The degree to which these biological factors influence waitlist placement must be accounted for in any model for the measure to be a valid representation of wait-listing. Moreover, transplant centers assess a myriad of demographic factors—e.g., family support, ability to adhere to medication regimens, capacity for follow-up, insurance-related issues, etc. Given transplant centers consider these types of SDS factors, any wait-listing measure risk model should adjust for them.

2. KCP suggested certain methods for accounting for SDS factors.

KCP believes that it is appropriate to report measures – both at the facility and the public reporting level – stratified by SDS factors. We also reiterate our strong preference for adopting an SDS adjustment for those measures where it has been shown, or is clearly suspected based on research from other care settings, that SDS factors and not dialysis facility performance are driving differences in the outcomes being reported.

Some SDS factors have been identified as driving outcomes in a manner that results in certain measures not reflecting the quality care being provided by providers or suppliers. For dialysis patients, we believe that the following SDS factors, at minimum, likely impact outcomes:

- Income, e.g., dual eligibility/low-income subsidy;
- Race and ethnicity;

- Insurance status at dialysis initiation; and
- Geographic area of residence.

We believe that each of these factors should be studied. While they are likely to overlap in some ways, they may not always do so. Additionally, we do not believe this is an exhaustive list and would like to work closely with CMS as it and the community review the current measures to determine if there might be other factors that might also drive outcomes regardless of the quality of care being provided.

In terms of collecting such data, we believe that it should be fairly straightforward for CMS to use its data to identify dual eligibility/low-income subsidy data, as well as geographic area of residence. We know from our experience with the ESRD Prospective Payment System (PPS) and the consideration of adopting a race/ethnicity payment adjuster that it can be difficult to collect such data. However, we believe that patient self-reporting is the most appropriate way to collect such data.

Adjusting measures for SDS factors is important, but CMS should also consider how it could provide “targeted technical assistance to facilities that disproportionately serve beneficiaries with social risk factors to improve quality and ensure they can successfully participate in the reporting required for the ESRD QIP,” as recommended by the ASPE report. We also agree with the ASPE report’s recommendation that innovative care models could help “achieve better outcomes for beneficiaries with social risk factors,” which is one of the reasons KCP has supported efforts to allow dialysis facilities and nephrologists to lead and participate in such programs. Even so, SDS factors will continue to influence performance scores for a significant portion, if not most, patients in the Medicare fee for service program. Thus, it is critically important that CMS provide sufficient funding to care for these patients through the Medicare ESRD PPS and not reduce these rates directly through reductions in the base rate or indirectly through the application of case-mix adjusters that result in dollars being removed from the rate.

Finally, we also agree with the ASPE report that suggests that HHS support “further research to examine the costs of caring for beneficiaries with social risk factors and to determine whether current payments adequately account for these differences in care needs.” KCP has strongly supported legislation, most recently introduced in the U.S. House of Representatives, H.R. 2644 “The Chronic Kidney Disease Improvement in Research and Treatment Act of 2017” that includes provisions that seek to improve patients’ lives and quality of care through research and innovation, as well as better understanding how the progression of kidney disease and treatment of kidney failure in minority populations.

KCP is pleased that CMS plans to work with the kidney care community generally and urges CMS to work with KCP and the KCQA more specifically, to evaluate and develop appropriate SDS factor stratifications and/or adjusters for measures. We strongly encourage CMS to review, respond to, and implement these recommendations as part of this year’s final rule.

B. KCP supports improving demographic data collection and recommends the use of Z-codes.

KCP appreciates the request to better understand how social, psychological, and behavioral data elements can be collected to help improve the ESRD quality programs. We recommend collecting social determinants of health data using Z-codes to account for and report on these factors, including housing or financial insecurity, minimal caregiver support, other mental and certain physical illnesses, or advanced age. Z-codes already exist and can be easily incorporated into current programs. The information collected could be used to identify and develop risk adjusters, as well as to address other patient-center priorities, such as reducing barriers to home dialysis and transplant.

C. KCP conceptually supports the creation of an ESRD facility equity score to synthesize risk across multiple social risk factors, but would need to understand the specifics before completely endorsing the score.

Consistent with our comments on the ETC Model, KCP supports in principle the development of a facility equity score that could address risk across multiple social risk factors. As described in the previous section of this letter, these factors should be taken into account for some quality measures, but not necessarily all. We also recognize that developing such a scoring methodology may be challenging. We encourage CMS to work with KCP and the community to identify the social risk factors that would be used for such a score, how they would be weighted, how they would interact with the current quality scoring methodologies, and other aspects of the program. To ensure patient and provider understanding and support, it will be important to have a transparent process with meaningful opportunities for comments and suggestions, even outside of the rulemaking process. It will also be important that these comments are taken into account and when appropriate incorporated into the final product. Understanding the details is essential to determining whether or not KCP and its members would ultimately support the score.

Since the inception and early implementation of the ESRD QIP, KCP has recognized that the program should identify facilities that are struggling to meet achievement and improvement benchmarks and implement programs to help them improve. Conceptually, efforts to help facilities with low equity scores improve over time is consistent with this longstanding position.

There are two major steps we believe should be taken to help these facilities. First, we believe that the dollars removed from the ESRD program because of cuts imposed through the QIP penalties should be returned to the system. Those facilities attaining the benchmarks could receive add-on payments rewarding them for their high achievements. In addition, some dollars could be allocated to a pool to help low-performing facilities improve. Second, many of the barriers are not medically driven. These can include access

to housing, dedicated care partners, nutrition, and transportation. As noted in other parts of this letter, federal fraud and abuse laws often prohibit dialysis facilities and nephrologists from working to address these issues. We ask that CMS engage with KCP to find ways to eliminate the restrictions we have already identified.

D. While KCP supports efforts to vaccinate dialysis patients, we do not believe a QIP measure is necessary or will help advance the goal.

KCP believes that patients and health care professionals should follow the CDC guidelines for vaccination, including vaccinations against COVID-19. KCER data coupled with infection rates that mirror those in the surrounding local community demonstrate that dialysis facilities are not spreading the disease, but rather that patients and health care professionals are more likely than not being infected outside of the facility. However, we recognize that dialysis facilities often serve as a patient's primary site for health care and, as such, can offer important preventative services like vaccinations. We supported the efforts of patient groups, dialysis facilities, and health care professionals to get vaccines into dialysis facilities to help reduce access barriers that patients receiving dialysis have faced in terms of getting vaccinated earlier this year. Although it took several months to get the federal government to authorize this approach, our members were finally permitted to administer vaccines in dialysis facilities. The effort has been successful, but we recognize more can be done.

The gap between the vaccinated and unvaccinated in both patients and health care professionals mirrors the gap in the country. We continue to encounter vaccine hesitancy among our patients and some of the dialysis facility health care professionals and staff. As we continue our efforts to promote vaccination among these groups, we do not believe that an ESRD QIP measure adopted for a future year would be helpful in addressing the gaps we have identified. In the short-term, it will be extremely difficult to specify the numerator given that the CDC rules around vaccination are continuing change, which is to be expected during a pandemic. These changing guidelines also make it difficult to understand how any measure would be valid or reliable as the rules upon which they are based are in flux. The different acceptance of vaccines in different parts of the country will also make it difficult to establish appropriate benchmarks.

We are also concerned about the unintended consequences of such a measure in the ESRD QIP. Dialysis facilities, like other health care providers in the country, are experiencing a work force shortage. We are concerned that those who refused to get vaccination (but would otherwise have taken precautions including regular testing and masking) will simply quit, creating other serious problems.

Given all of these challenges and the hesitancy of the NQF MAP to recommend the measures, KCP requests that CMS not pursue adding them to the QIP. Rather, we suggest coordinating efforts with CDC and other federal agencies to develop targeted campaigns to

reduce vaccine hesitancy. Additionally, CDC could adopt an NHSN staff reporting program that could be modeled off influenza vaccination program. While specifying a measure would still be difficult given the current moving target of what it means to be vaccinated, a reporting measure outside of the ESRD QIP could be informative at some point. We believe that such programs would be more effective at achieving higher vaccine levels than a quality measure being added to an already overburdened value-based purchasing system.

E. KCP supports efforts to move to a fully digital quality measurement (dQM) system for reporting and value-based purchasing programs by 2025.

KCP supports the definition of dQM as “a software that processes digital data to produce a measure score or measure scores.”⁵⁰ We agree that data sources should include administrative systems, electronically submitted clinical assessment data, case management systems, electronic health records, instruments such as medical devices or wearable devices, patient portals or applications, health information exchanges or registries, and other sources.

Given the strain on existing resources, both financial and workforce, it is essential that, in moving to dQM systems, CMS leverage existing interoperability sources as well as advances in technology. We agree that it is promising to define and deploy dQMs to interface with Fast Healthcare Interoperability Resources (FHIR)-based Application Programming Interface (APIs). Adoption of FHIR for ESRD facilities and providers has not occurred because of CMS’s focus on first CROWNWeb and now EQRS. As noted below, the burden of shifting to yet a third system (FHIR) when the second (EQRS) is not finalized may outweigh the immediate benefit of taking this step.

KCP agrees that it is essential to align the data needed for quality measurement with interoperability requirements. The kidney care community has been aligning its data since the beginning of CROWNWeb, which predated the QIP. We continue that process with the EQRS. The work of the dialysis facilities and the Renal Healthcare Association (a member of KCP) have resulted in standardized batch reporting to CMS for quality measures for more than 90 percent of all U.S. dialysis clinics. While not in a standard FHIR format, the batch submission work has led to the adoption of a standard data format in EQRS for quality reporting in ESRD. It would be unduly burdensome to undue this just completed work.

While we support coordination of data, we are concerned that any benefit of shifting from the recently finalized EQRS standard data format to FHIR will result in significant burden without improving data transmission efficacy for quality reporting. Additionally, if the community were to shift to FHIR-based reporting, the community would need to maintain a new ESRD FHIR specification which would need to be regularly updated as CMS

⁵⁰*Supra* note 4 at 36372.

added new data elements. The utility of an ESRD-specific FHIR standard outside of quality reporting to CMS is very limited, making the FHIR quality reporting work even more burdensome. Given the successes of the current system and limited benefit, we do not think it makes sense to shift at this time.

Through the work with KCQA, KCP has demonstrated strong support for patient generated health care data being part of the QIP and other ESRD quality programs. We have shared our recommendations related to a patient-reported outcomes measure as well. However, current tools are limited as to what data are available and some fields with more detailed individual patient responses cannot be easily standardized. Yet, they remain valuable and should be shared with providers. At this time, we do not think there is much value of standardizing the reporting of these fields via FHIR, given the EQRS standardization note above.

KCP continues to be concerned that some of the measures used in the ESRD QIP and Five Star programs are not valid because the underlying data sources lack validity. Our comments in this letter related to the BSI NHSN measure are a good example of these concerns. Our members have worked extensively with CROWNWeb and EQRS to ensure the validity of the data. They remain committed to continuing these efforts as new formats are adopted as well. Yet, as noted already, the community just completed this multi-year work for EQRS data. As such, it would be difficult to ask them to replicate this work to FHIR given the limited benefit noted already.

Because CMS already has standardized data for 90 percent of the dialysis facilities and the data are transmitted via EQRS, it is not clear what benefit shifting to a standardized FHIR would provide. Similarly, given that the EQRS data specification covers over 90 percent of clinics today, it is not clear that there would be any incremental gains from the system being considered. The community has successfully used the data sources and coordinated with CMS for EQRS standardization to develop measures and quality tools and to perform public health research. For these same reasons, both existing data standardization and availability of required data in provider EMRs or CMS claims data, there is no need for data aggregators for the ESRD quality program.

In sum, KCP supports using dQM, but unlike other parts of the health care industry, the kidney care community has already achieved many of the goals CMS is seeking to accomplish. We ask that CMS not reinvent the wheel, but rather continue to work with the community to address the next generation of quality and data policies.

VII. Conclusion

Thank you again for the opportunity to provide comments on the Proposed Rule. We appreciate the RFI and efforts to address many outstanding concerns KCP has raised about the ESRD QIP. Please do not hesitate to reach out to Kathy Lester, our counsel in Washington, 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

Appendix: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Pediatric Nephrology
Amgen
Ardelyx
American Society of Nephrology
AstraZeneca
Atlantic Dialysis
Baxter
BBraun
Cara Therapeutics
Centers for Dialysis Care
DaVita
DialyzeDirect
Dialysis Patient Citizens
Dialysis Vascular Access Coalition
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
NATCO
Nephrology Nursing Certification Commission
Otsuka
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma