KIDNEY CARE PARTNERS

August 4, 2022

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

Re: CMS–1768–P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure,

On behalf of the more than 30 organizations working together to advance kidney care through Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments on the "End-Stage Renal Disease [ESRD] Prospective Payment System [PPS], Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury [AKI], End-Stage Renal Disease Quality Incentive Program [QIP], and End-Stage Renal Disease Treatment Choices [ETC] Model Proposed Rule"[1] (Proposed Rule). This letter focuses on the measure and structural aspects of the proposals related to the ESRD QIP. Our comments on the remaining provisions of the ESRD QIP, ETC Model, and the ESRD PPS will be provided in separate letters.

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

In this letter, KCP provides comments on the following proposed policies:

- The flexibilities for the ESRD QIP in response to the COVID-19 public health emergency (PHE);
- The technical measure specifications for the Standardized Hospitalization and Standardized Readmission Ratio/Rate measures for PY 2023 and PY 2024;
- The updates to the performance standards for PY 2023;
- The COVID-19 Healthcare Personnel (HCP) Vaccination reporting measure, as well as comments related to the existing measure set;
- The performance standards, eligibility requirements, and payment reduction scale for PY 2025; and

[1] 87 *Fed. Reg.* 38464 (June 28, 2022).

- The updates for the PY 2026 QIP.

We plan to submit a second letter specific to the RFI and ETC proposals, including:

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

KCP appreciates the ongoing opportunity to work with the Biden-Harris Administration as it seeks to improve access to high-quality kidney care and address inequities in the delivery of health care that those individuals living with kidney disease and kidney failure too often experience. As CMS notes in the preamble of the Proposed Rule, Fee-for-Service (FFS) "beneficiaries receiving dialysis are disproportionately young, male, disabled, and African- American, have low income as measured by dual status, and reside in an urban setting."[2] These are the very individuals who have had to face the greatest and most severe inequities in the delivery health care. We reiterate our commitment to working with the Administration to address kidney disease prior to the time when an individual's kidneys fail and they require dialysis or a transplant. We also continue to support efforts to improve access to transplants. As a community, we know that the best treatment option for patients is a transplant, but as this Administration has recognized, barriers in the current transplant system result in far fewer individuals with kidney failure receiving a transplant than those who need them.

While these pre-dialysis and transplant issues are important to address, it is essential to protect access to dialysis, given that more than 70 percent of individuals diagnosed with kidney failure require three-to-four-hour dialysis treatments at least three times a week in order to stay alive.[3] The ESRD QIP value-based purchasing program provides individuals who require dialysis, their families, care partners, and the health care professionals with whom they work important quality performance information that promotes patient-driven decision-making. Since its inception, CMS' implementation of the

[2] 87 *Fed. Reg.* at 38500.
[3] NIDDK. "Kidney Disease Statistics for the United States." https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease (Last Updated September 2021).

ESRD has succeeded in achieving this goal. However, it is important to streamline this program and ensure that the performance measures are meaningful to individuals who require dialysis and reflect the actual performance of dialysis facilities. In this letter, KCP recognizes and appreciates the efforts CMS has made to address some of the ongoing concerns the kidney care community shares with regard to the use of certain measures; we also highlight our recommendations to address those that have not been resolved.

I. KCP Seeks the Release of the Final Measure Specifications.

As a threshold matter, KCP reiterates our request that CMS provide the specifications for all of the measures that are proposed for PY 2025 and PY 2026. While we appreciate having the draft specifications for measures previously included in the QIP, we have not been able to locate the specifications for the SDoH measures. Without these specifications we do not have the required opportunity to provide comments.

II. KCP Thanks CMS for Recognizing the Continuing Need for Flexibilities for the ESRD QIP in Response to the COVID-19 PHE and Recommends an Additional Measure for Suppression and that CMS Not Enforce the QIP Penalties for Payment Year (PY) 2023.

A. KCP Recommends Not Scoring and Not Penalizing Facilities in PY 2023.

As CMS has observed, the impact of the COVID-19 pandemic on the health care remains substantial, which the Secretary most recently recognized by extending the PHE an additional three months. Individuals living with kidney disease are particularly at-risk for infection, re-infection, and experiencing complications from the disease. While the kidney care community has joined together and worked diligently to reduce that risk, the disease is particularly impactful for individuals living with kidney disease. The experience of the last two years of the pandemic affirm that these individuals are more likely than other Americans to contract COVID in their communities and experience higher morbidity and mortality rates.

Even though it is helpful to suppress specific measures once again this year, we also believe it is important to suspend the penalties for PY 2023 as CMS did for PY 2022. Once again, the pandemic has negatively impacted the ability of facilities to submit data through the EQRS system. The CMS EQRS group has reported a significant decrease in data submitted in the last year. This decrease means that the data will be skewed.

In addition, suppressing nearly half of the QIP measures as proposed will skew the scores and not present a meaningful picture of the quality performance of facilities. KCP supports suppressing the measures CMS has proposed and recommends also suppressing the Standardized Fistula Ratio (SFR) measure, as we discuss below. CMS correctly recognizes that the pandemic has had a significant impact on these measures. While we agree they should be suppressed, suppressing these measures has such an enormous

impact on the calculation of the minimum total performance score (mTPS) that it argues for not scoring the facilities on the remaining measures and not implementing penalties for PY 2023. For example, the weight of the Clinical Depression reporting measure shifts from 2 percent to 35 percent, making it the most weighted measure in the ESRD QIP for PY 2023. Yet, this measures records only whether a facility screens a patient for depression rather than achieving a particular clinical outcome. The next highest weighted measure would be the STrR at nearly 14 percent. While CMS indicates that the validity concerns with this measure have been addressed, there is no publicly available data demonstrating that this measure is actually assessing facility performance as opposed to hospital's utilization of transfusions.

These are only two examples how trying to score facilities on the remaining measures will skew the results in a way that seem inconsistent with CMS' goals for the ESRD QIP. Applying the penalties based upon the skewed results will not drive quality as the Congress intended the QIP to do. Therefore, we ask that CMS not score facilities for PY 2023 and not apply penalties.

Not applying the penalties for PY 2023 would parallel the Hospital Inpatient Prospective Payment System policy for the hospital value-based purchasing program. In that program, CMS proposes to suppress several measures and not to score the hospitals and not to penalize them. CMS states in the inpatient hospital proposed rule that "Awarding negative or positive incentive payment adjustment percentages using TPSs calculated using the current scoring methodology would not provide a representative score of a hospitals' overall performance in providing quality of care during a pandemic."[4] The same is true for dialysis facilities as well.

B. KCP Supports Suppressing the Measures as CMS Proposes and Recommends that the SFR Measure Be Suppressed.

KCP thanks CMS for suppressing the measures listed in the proposed rule, including the Long-Term Catheter measure due to significant deviation in national performance during the pandemic. However, we are puzzled as to the decision not also to suppress the SFR. CMS notes that a steep increase in catheter rates during CY 2021 indicates that the COVID-19 PHE continues to impact the ability and/or desire of ESRD patients to seek permanent vascular access placement. Because the two measures are directly linked, it follows that the same PHE-related factors that are *increasing* catheter rates will also necessarily and materially *decrease* fistula rates. We, thus, reiterate our prior concern that

[4]CMS. "Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation Proposed Rule." Display Copy 873-74 (2022).

there will be significant deviation in national performance on the SFR during the PHE that will likely be significantly worse when compared to historical performance during the 2019 baseline period; we again urge CMS to suppress *both* access measures in PY 2023.

III. KCP Continues To Support the ESRD QIP Value-Based Purchasing Program and Reiterates our Recommendations to Make the QIP More Meaningful for Individuals Relying Upon Dialysis Treatments.

KCP remains strongly supportive of the ESRD QIP. We believe that the Medicare ESRD QIP, as the first Medicare value-based purchasing program, has provided a foundation for the ongoing CMS efforts to expand value-based purchasing successfully within the Medicare program as a whole. As we have highlighted in previous letters, KCP encourages CMS to continue its work and support that of the community to transform the QIP to make it more meaningful for individuals receiving dialysis by focusing on measures that matter, those that are actionable by dialysis facilities, and that are scientifically reliable and valid so that the reflect performance accurately. To that end, we ask once again that CMS reduce the measures included in the ESRD QIP and transfer some measures to the Facility Compare Five Star program. Our comments below reflect this consensus position of the kidney care community. Implementing these recommendations would also allow the community to address some of the gaps in treatment and care options to improve outcomes and address disparities in health care. These recommendations apply to the proposals for PY 2023 and subsequent years.

A. KCP Supports the Proposal to Shift the Standardized Ratio Measures to Rates and Asks that CMS Maintain a Consistent Denominator to Achieve the Goals Associated with Using Rate Measures.

KCP thanks CMS for addressing our recommendation to shift the standardized hospitalization ratio and standardized readmissions ratio measures to rates. Presenting rate measures will allow for the year-over-year comparability at the facility level. We agree with CMS that "expressing the measure performance as a rate instead of a ratio would communicate the same information in a clearer way."[5] To achieve these goals, it is essential that the denominator remain the same and not changed year over year. Keeping the denominator the same will also allow for facilities to compare their performance and take the actions necessary to improve outcomes when needed. We also ask that to the extent CMS is using other standardized ratio measures that it apply this policy with the KCP denominator recommendation to those measures as well.

We agree that transitioning from ratios to rates will improve the interpretability of standardized ratios currently included in the QIP and public reporting and will assist dialysis providers in using the data to continuously improve quality. We understand that the standardized ratio will be transformed to a rate by multiplying the ratio by the national

[5] 87 *Fed. Reg.* 38539.

rate (of hospitalization, readmission, *etc.*) during the performance year. The resultant quantity is a rate with a conceptual basis, not a concrete basis, insofar as the rate reflects what would occur in a facility with patients whose characteristics reflect the national population of dialysis patients.

We understand that the established approach in the QIP will require rates to be estimated not only in the performance year, but also in an earlier baseline year (*e.g.* 2019) that establishes performance standards. This creates a challenge, insofar as the national population of dialysis patients may differ between these two years. To address this point, we suggest that CMS adopt the same "adjustment" factor as is used in the Star Rating Program.[6] That is, to translate the adjusted rates in the performance year to the same scale as the adjusted rates in the earlier baseline year, the adjusted rates in the performance year should be *divided* by the following factor:

$$\frac{\text{National event rate during the performance year}}{\text{National event rate during the earlier baseline year}}$$

The above factor can be interpreted as a measure of the relative risk profile of the dialysis population between the performance year and the earlier baseline year.

B. KCP Supports Including the COVID-19 Healthcare Personnel (HCP) Vaccination Reporting Measure in the ESRD QIP beginning with PY 2025.

Early in the pandemic, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) prioritized in Phase 1 distribution of COVID-19 vaccines to patients with chronic kidney disease (CKD) and health care professionals who care for these patients. ACIP's prioritization of dialysis patients recognized that dialysis patients are especially vulnerable when it comes to the impact of COVID-19.

The CDC recognizes the importance of vaccinations among dialysis patients. According to the CDC, the age and health status of dialysis patients place them at high risk for serious illness and death related to COVID-19; people on dialysis who get COVID-19 have a 50 percent hospitalization rate and a 20–30 percent mortality rate.[7] The CDC also recognizes that individuals who rely upon dialysis are disproportionately Black (34 percent) and Hispanic (19 percent).[8] Because the majority of patients receive dialysis in a facility or visit a facility to receive laboratory tests and other check-ups, they have not had the option of isolating at home during surges in their communities.

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[6]Technical Notes on the Updated DFCC Star Rating Methodology. Available at https://dialysisdata.org/content/dfccmethodology.
[7]CDC. "Vaccinating Dialysis Patients and Healthcare Personnel." https://www.cdc.gov/vaccines/covid-19/planning/vaccinate-dialysis-patients-hcp.html. (2021).
[8]*Id.*

Dialysis facilities have worked diligently to reduce the spread of the disease through administering vaccines to patients and the health care professionals working in their facilities. Even so, the community continues to face significant opposition to vaccines in certain areas of the country. We ask CMS, the CDC, and other federal agencies to expand efforts to support vaccines and improve public understanding about their importance in protecting against morbidity and mortality.

C. KCP Remains Concerned about the Use of the Standardized Transfusion Ratio (STrR) Measure as a Clinical Measure for PY 2025, Even if It Is Transformed into a Rate Measure; KCP Recommends Replacing the STrR with a Hemoglobin (Hgb) Less than 10 g/dL Measure.

KCP recognizes the importance of including an anemia management measure in the ESRD QIP, but remains concerned about using the STrR because it does not reflect the actions dialysis facilities take or do not take to manage anemia in their patients. We strongly urge CMS to adopt a Hgb < 10 g/dL measure that does reflect the actions taken by facilities and will provide more transparency than the STrR is able to provide. If the Administration seeks to address any gaps in anemia management, it is critically important the anemia management measure track dialysis facility activities rather than hospital decision-making. The STrR is based on transfusion information to which dialysis facilities do not have access because this information 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.

In addition, the STrR does little to improve patients' hemoglobin levels, which we know is directly linked to health-related quality of life outcomes such as fatigue and being able to engage in activities of daily living. CMS data show very little movement in terms of quality improvement as a result of the STrR replacing a hgb measure in the QIP. The mean of the observed-to-expected ratios across dialysis facilities declined minimally in a recent three-year analysis, from 22.5 in 2016 to 21.0 in 2018.[9] Lower hemoglobin levels can have a significant impact on patients' quality of life. As CMS looks to shift toward more patient-reported outcome measures, getting the right anemia management measure in the ESRD QIP should be prioritized.

Unfortunately, the STrR has not addressed health inequities that many dialysis patients have experienced**.** 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. Hemoglobin values less than 10 g/dL are more prevalent in Blacks, afflicting 26.1 percent and 27.2 percent of Black hemodialysis and peritoneal dialysis patients in 2019, respectively, compared to 23.8 percent and 20.1

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

percent in Whites.[10] For transfusions, the differences are smaller and result from decisions made in the hospital rather than by the dialysis facility. For example, the monthly percentage of dialysis patients who received one or more transfusions in 2019 was 3.3 percent for both Blacks and Whites, compared to 2.5 and 2.4 percent of Hispanic and Asian dialysis patients, respectively .[11]

The QIP which seeks to incentive improvements in managing anemia among individuals receiving dialysis should include an anemia management measure focused on the management of anemia by dialysis facilities, rather than hospital and hospitalists' practices.

In previous letters, KCP has raised concerns about under-counting with the STrR because of well-documented differences in coding practices for transfusions by hospitals. CMS has indicated that these concerns have been addressed; however, the documentation of these improvements has not been publicly shared. Even if these coding concerns are addressed, they do not resolve the actionability concerns that are necessary to drive outcome improvements for Black and Hispanic patients.

D. KCP Supports Shifting the Hypercalcemia Measure to a Reporting Measure, Yet Urges CMS to Replace It with a Serum Phosphorus Measure.

KCP thanks CMS for acknowledging the limitations of the measure and that other bone mineral measures would be more informative and effective. This topped out measure fails to provide meaningful information to individuals relying upon dialysis or the health care providers managing their treatments. KCP reiterates that it would be appropriate, for purposes of having a bone mineral metabolism measure, to use the serum phosphorous measure (Number of months in which a facility reports serum or plasma phosphorus in CROWNWeb at least once during the reporting month for adult (≥18 years of age) peritoneal dialysis and hemodialysis patients. NQF #: 0255) in place of the hypercalcemia measure as a reporting measure in the QIP for PY 2025. Even though the measure is in reserve status, physicians actually rely upon the serum phosphorous measure to make clinical decisions. The Kidney Care Quality Alliance (KCQA) has convened a technical expert panel to review measures in the bone mineral domain and make recommendations for a meaningful measure in this area where gaps in treatment remain, especially when it comes to individuals who are Black and Hispanic. We look forward to collaborating with the Agency on this important work.

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[10] United States Renal Data System. 2021 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, 2021. Chap. 3. See Figure 3.1dc by Race.
[11] *Id.*

E. KCP Encourages CMS to Revise the PY 2025 Measures to Create a Parsimonious, Meaningful, Streamlined Measure Set that Addresses Health Inequities and Promotes Transparency and Quality Improvement Activities.

Once again, KCP requests that CMS refine the ESRD QIP measure set to make it more meaningful in three ways. First, we ask that CMS eliminate the inconsistencies and conflicts that have arisen among the various Medicare ESRD quality programs. This step would make facility performance easier to understand for patients, health care professionals, and care partners. Second, a smaller measure set would place more emphasis on those measures that matter by addressing gaps in care. Third, this more meaningful set would be better suited to drive improved outcomes and address inequities in care.

In previous comments, KCP has offered an approach that would allow the Facility Compare Five Star program and QIP to achieve the independent goals CMS has identified for each and that would preserve the Congressional intent for the ESRD QIP. Under this model, KCP recommends that the Facility Compare focus on meaningful measures that are not used in the ESRD QIP and provide 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.

We recommended the following initial set of measures for each program, based upon the measures that are in the programs today.

ESRD QIP Measures	**ESRD Facility Compare Five Star Measures**
Standardized hospitalization rate measure	KCQA UFR Measure
Standardized readmissions rate measure	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)

ESRD QIP Measures	ESRD Facility Compare Five Star Measures
Patient Experience of Care: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Clinical Measure (modified to incorporate the experience of home dialysis patients as well)	Fistula measures
Hgb < 10 g/dL	Clinical Depression Screening and Follow-Up Reporting Measure
Serum phosphorous	Standardized Mortality Rate measure
Transplant referral measure, including assistance with first visit (KCQA has develop a measure set it is currently testing before submitting to NQF)	Patient Reported Outcome Measure (when developed and endorsed)
COVID-19 health care professionals vaccination reporting measure	

Below, we summarize suggested modifications to each these measures to address underlying concerns with their current specifications that reduce their usefulness in meeting CMS' goals of including them in the ESRD QIP. 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.

1. For the SHR and SRR Measures, KCP Supports Including a Covariant Adjustment for Patient History of COVID-19.

A hospitalization measure is critically important for driving quality improvement for individuals receiving dialysis and for informed patient decision-making. As noted in the previous section, KCP is pleased CMS has proposed shifting these two measures to rates.

KCP supports the proposal to modify the SHR and SRR measures to include a covariant adjustment for patient history of COVID-19 beginning in PY 2025, although we would recommend including the adjustment sooner if possible. We also request that CMS make supporting analytics available to allow for stakeholder review of the impact on model performance. In addition, KCP recommends that CMS risk adjust these measures using race and ethnicity, as it current does for 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.

It is important to make sure that these measures are actionable by dialysis facilities and not reporting on other variables that could confound the reports. The most recent pre-pandemic data showed that the adjusted rates of overall hospitalizations among Medicare ESRD beneficiaries were high among all patients[12] when compared with the general Medicare population.[13] 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.

While KCP is encouraged by the proposals related to converting the ratio measures to rates, this shift does not address the fact that the SRR and SHR measures are not reliable, with the most recent (2018) overall inter-unit reliability (IUR) of 0.35 and 0.53, respectively. (Statistical literature traditionally interprets a reliability statistic of 0.50-0.60 as "poor."[14]) 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 disproportionally 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.

2. Percentage of Prevalent Patients Waitlisted (PPPW).

KCP supports including transplant measures in the ESRD QIP, but remains concerned about the use of the PPPW in the ESRD QIP. To address the short-comings of the PPPW, which the NQF has formally rejected as lacking validity, the Kidney Care Quality Alliance (KCQA) convened a public expert panel to develop a set of transplant measures. The set includes a Transplant Waitlisting Plus Referral measure that is the percent of all

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[12] *Id.* see Figure 3.1b, by Race.
[13] 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 July 18, 2022).
[14] Adams JL. The Reliability of Provider Profiling: A Tutorial. Santa Monica, California:RAND Corporation. TR-653-NCQA, 2009.

dialysis patient-months attributed to a dialysis facility during the measurement year in which the patient is EITHER already on the kidney and/or kidney-pancreas transplant waitlist OR has a documented referral to a transplant center for evaluation. It also includes a Percent Waitlisted Among Referred Measure that is the percent of all dialysis patients with a documented referral to a transplant center for evaluation who were placed on the kidney and/or kidney-pancreas transplant waitlist during the measurement year. The KCQA is testing these measures this fall and plans on submitting them for NQF consideration for the Spring 2023 Cycle. We believe that these measures will not only address the validity concerns associated with the PPPW measure, but will also be more effective in incentivizing improvements by dialysis facilities because they are linked to actions dialysis facilities can take rather than reporting on the actions of transplant centers, which is a concern with the PPPW measure.

Some in the community have suggested over the years that having some type of metric is better than having no metric. That is not true, especially when the metric will mislead patients as they try to make informed decisions about their health care. The PPPW lacks validity. Lacking validity means that this measure does not provide an accurate assessment of facility performance. The 2021 CMS Impact Assessment shows a relatively low score of 19.2, when larger results indicate better performance.[15] 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."[16] If patients or other stakeholders were to use it to make medical decisions, they would be using invalid information.

KCP remains deeply troubled by the use of the PPPW in the ESRD QIP because it does not address the very health disparities at the core of CMS' efforts. The disparities in waitlisting are pervasive and well-documented, as we noted in our comment letter last year.[17]

While we reiterate our concern that not enough is being done to streamline and improve waitlist criteria to promote greater access to waitlists for people of color, it is important that CMS adopt measures in the ESRD QIP that target the actions dialysis facilities take (or do not take) to promote transplant. Individuals who require dialysis and want to select facilities that have "better" performance cannot obtain the information they need from the PPPW measure.

Given the KCQA timeline, we encourage CMS to work with the KCQA and propose that the transplant measure set be adopted to replace the PPPW in the ESRD QIP for PY 2025.

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[15] CMS. "2021 National Impact Assessment of the Centers for Medicare & Medicaid Services Quality Measure Report Appendix" (2021).
[16] NQF, "NQF Report of 2018 Activities to Congress and the Secretary of the Department of Health and Human Services" (March 1, 2019).
[17] USRDS, *supra* note 10. see Figure 3.1b, by Race.

3. Standardized Fistula Rate (SFR) and Long-Term Catheter Rate (LTCR).

KCP remains committed to reducing the use of catheters for dialysis access. Recent peer-reviewed articles have emphasized that closing the gap in this aspect of care would be accomplished better by focusing value-based purchasing measures on reducing the long-term catheter rate alone. Focusing on this measure would still achieve the common goal of reducing catheters in favor of grafts and fistulas, but increase the weight – and thus the incentive – associated with reducing the use of catheters. Closing this gap is also critically important to address the health inequities experience by patients of color today when it comes to the use of catheters. For these reasons, KCP asks CMS to move the fistula measure to Facility Compare and adjust or stratify the catheter for age, race and ethnicity, and insurance status prior to dialysis initiation.

CMS' data shows that the combined metrics have not moved the needle on this gap in care sufficiently. A 2021 publication assessing the impact of the QIP on vascular access provides additional data that indicate performance has not improved under the program.[18] The problem was greatest for individuals of color. The researchers found that 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$). These vascular access discrepancies have been consistent for both incident and prevalent over the past decade.[19]

We encourage CMS to stratify the catheter measure as well to provide clear results that would allow healthcare providers and other stakeholders to identify and prioritize differences in care, outcomes, and experiences across the different racial and ethnic groups. This level of information is needed to allow them to develop and implement equity-focused practices to address disparities and better understand the experiences of patients from communities of color.[20] 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.

Prioritizing the long-term catheter measure in the QIP would also align the program with the KDOQI recommendations. In its 2020 publication, KDOQI outlined a patient-focused approach for providers to consider not only the current vascular access, but also the patient's subsequent needs within the context of a comprehensive and individualized

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[18] 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.
[19] USRDS, *supra* note 10. see Figures 4.2 and 4.6.
[20] See 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 July 18, 2022).

End-Stage Kidney Disease (ESKD) Life-Plan.[21] Reducing catheters is consistent with this approach, while over-emphasizing fistula placement for all patients runs counter to it.

4. Patient Experience Measure.

KCP believes it is critically important to measure patient experience related to their dialysis treatments and their interaction with nephrologists. We are pleased that the contractors continue to work on truncating the tool to address the well-documented fact that the current tool is too long. Pre-pandemic 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.[22] 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. As CMS has recognized, these rates have fallen even more during the pandemic.

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. In fact, the current tool marginalizes people of color. 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.[23] This situation should not be perpetuated. In addition, the current tool excludes home dialysis patients, reducing the power of their voice in the process.

CMS could begin to solve this problem even for PY 2024 by take two simple steps. First, ICH-CAHPS should be administered to patients once a year (not twice) to reduce burdens on patients. Second, when asking patients to complete the survey, the contractor should divide the survey into the three validated section and field each one. CMS has recognized in its own publications the validity of separating the survey into different sections for analysis.[24] 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.[25] Then, while a facility would be surveyed on the complete tool, any one patient would have to complete only one-third of the questions. We continue to recommend that CMS exclude the homeless to whom the survey cannot be distributed, given that facilities are not allowed to provide the survey directly to patients.

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[21] Lok CE, Huber TS, Lee T, et al. KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. *Am J Kidney Dis.* 2020;75(4)(suppl 2):S1-S164.
[22] Dad 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.
[23] *Id.*
[24] 2021 CMS Impact Assessment of the ICH-CAHPS measures
[25] *Supra note 17.*

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.

In addition to reducing the burden on patients, the community asks CMS to provide access to the surveys' results so that they can be used to improve care. Currently, facilities never see the results and cannot communicate with patients about the results. This situation leaves patients feeling as if they had wasted their time completing the survey. Patients want to be heard, and facilities want to be able to hear what they are saying works and does not.

Administration of the ICH-CAHPS survey should be tailored to address these problems and does not marginalize the voices of patient voices.

5. Kt/V Comprehensive Clinical Measure

KCP strongly supports efforts to expand access to home dialysis modalities to individuals for whom it is the right choice. We remain deeply concerned that the current Kt/V comprehensive measure conceals home dialysis performance by combining this information with in-center dialysis results. Therefore, we renew our strong recommendation that CMS use the distinct adult hemodialysis and peritoneal dialysis adequacy adult and pediatric measures endorsed by the NQF. While the vast majority of patients do receive adequate dialysis (urea clearance),[26] this pooled approach to reporting eliminates the ability for patients, care partners, and stakeholders to determine performance on any specific patient population or dialysis modality. It also masks social disparities in terms of adequacy of dialysis. Patients should have access to 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.

6. Ultrafiltration Measure.

KCP continues to support the use of the KCQA ultrafiltration measure in the ESRD quality programs, but as noted above, believes it would be better suited as part of the Facility Compare program at this time. 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," KCP would support replacing the topped-out Kt/V measure with the UFR.

[26] USRDS, *supra* note 10.

7. NHSN Bloodstream Infection in Hemodialysis Patients Clinical Measure and NHSN Reporting Measure.

KCP reiterates our deep concern about the reliability and validity of the BSI measure. In the QIP, CMS is not using the measure adopted by NQF, but a modified version. The validity concerns identified by CDC's research show that the measure is not a valid representation of the care provided. These problems have not been resolved. Knowing the importance of this measure, the KCQA has convened an expert panel to review the measure and offer solutions to the validity problem so that the QIP can include a measure that is meaningful for patients, caregivers, and health care professions in addressing BSI.

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.

We reiterate our short-term solution that CMS 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.

8. Clinical Depression and Screening.

KCP renews its recommendation that the Clinical Depression and Screening Reporting Measure be shifted to the Facility Compare program in lieu of being used in the ESRD QIP. 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.[27] The QIP should focus on those measures where there are significant gaps in care, not on measures that are topped out.

9. Medication Reconciliation.

As the measure developer of the Medication Reconciliation measure, KCP continues to support its use in the ESRD quality programs, but recommends that it be placed in the Facility Compare program in lieu of being used in the QIP.

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[27] *Id.*

IV. KCP Supports Using CY 2019 Data to Update the PY 2023 and PY 2024 Performance Standards.

KCP supports CMS calculating the performance standards for PY 2023 using the CY 2019 data. We also support using CY 2019 for PY 2024. While CY 2019 data are not perfect, we reiterate that data collected during the pandemic have been skewed in ways that make it inappropriate to use them as a comparator.

V. KCP Supports the Proposals for PY 2025 for the Performance Standards and Payment Reduction Scale for PY 2025, but Reiterates Our Concerns that the Eligible Requirements Inappropriately Introduce Randomness into the mTPS and Penalties.

KCP appreciates that CMS continues to maintain the stability in the performance standards and payment reduction scale methodology. This consistency allows for year-over-year comparison of QIP results.

KCP reiterates our request that CMS address the problem of small numbers. We recognize that CMS does not propose an alternative in this rulemaking, but ask CMS to work with KCP to address the shortcomings of the current policy and propose modifications to address these in the rulemaking next year. We remain concerned that the reliance on an eligibility requirement set at 11 or more cases undermines the statistical reliability of the measure results. The current policy unfortunately does not eliminate the random results associated with small numbers. We understand the interest in allowing small facilities to report quality measures, but it is important that the outcomes do not reflect performance. Adopting 25 as the minimum number of cases would also be consistent with the way CMS has defined the minimum number for the Skilled Nursing Facility value-based purchasing program. We look forward to dialoguing with CMS on ways to address this concern and still allow for reporting by smaller facilities.

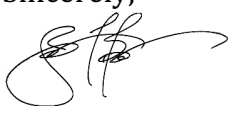
VI. KCP Supports CMS' Proposal for PY 2026 with the Caveat the Changes We Recommended in the Previous Sections of the Letter.

KCP appreciates the proposal not to make changes for PY 2026. Throughout this letter we have made recommendations for previous payment years that we ask be adopted and then incorporated into PY 2026, especially with regard to changes in the measures used for PY 2026.

VII. Conclusion

Thank you again for the opportunity to provide comments on the Proposed Rule. Our counsel in Washington, Kathy Lester, will be reaching out to schedule a meeting, but please do not hesitate to reach out to her if you have any questions in the meantime. She can be reached at klester@lesterhealthlaw.com or 202-534-1773.

Sincerely,



John Butler
Chairman

cc: Lee Fleischer, Director, Center for Clinical Standards & Quality
Michelle Schreiber, Director, Quality Measurement & Value Based Incentives Group

Appendix: KCP Members

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