



June 24, 2023

Partnership for Quality Measurement  
Battelle  
505 King Avenue  
Columbus, Ohio 43201

RE: Primary Care and Chronic Conditions Project Spring 2023 Cycle Early Comments

Kidney Care Partners (KCP) is a non-profit coalition of more than thirty organizations comprising the full spectrum of stakeholders related to dialysis care—patients and advocates, dialysis professionals, physicians, nurses, researchers, therapeutic innovators, transplant coordinators, and manufacturers. KCP is committed to advancing policies that improve the quality of care and life for individuals at every stage along the chronic kidney and end stage renal disease care continuum, from prevention to dialysis, transplant, and post-transplant care. KCP applauds Battelle and the Partnership for Quality Measurement (P4QM) for its commitment to serve as the new Consensus Based Entity (CBE) for the Centers for Medicare and Medicaid Services (CMS), and we appreciate the opportunity to comment on measures under review in the Primary Care and Chronic Conditions Spring 2023 Project. We commend Battelle and the P4QM for undertaking this vital work, and we offer comment on the three new renal measures being considered within the project:

- ESRD Dialysis Patient Life Goals Survey (#3742)
- Delay in Progression of Chronic Kidney Disease (#3753)
- Risk-Standardized Mortality Ratio for Late-Stage CKD and ESRD (#3754)

#### OVERARCHING ISSUES

KCP acknowledges there will be process and policy changes as the P4QM assumes its new role as CBE, and we look forward to working with Battelle as stakeholders navigate this transition. As a threshold matter, however, we are concerned that these three renal measures are not being considered within the Renal Project, to which all renal-related measures have traditionally been assigned. We note that the dialysis facility, in particular, is a unique, *tertiary* care setting guided by unique Federal regulations and a unique punitive payment system. ESRD Quality Incentive Program (QIP) penalties often disproportionately and paradoxically impact the most financially vulnerable facilities treating the most socially and medically disadvantaged patients.<sup>1</sup> The Renal Standing Committee was constructed to ensure that measures being considered for use in the QIP are technically appropriate for use in this singular patient population and specialized care setting and will not inadvertently perpetuate the very disparities CMS and P4QM are working to address. We strongly recommend these measures be properly reassigned to the P4QM *Renal* Standing Committee for endorsement consideration. Barring that, we urge P4QM to invite appropriate subject matter experts or sitting Renal Standing Committee members to participate in these measures' review.

Likewise, it is unclear if the Scientific Methods Panel (SMP) will continue its work under Battelle. If so, it is equally unclear whether these complex measures are slated for review by the Panel, as was the standard previously established by NQF. Each of these three measures requires interpretation of intricate risk model and/or methodologic and psychometric performance data; many stakeholders rely on the SMP's

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<sup>1</sup> Sheetz 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 Aug;174(8):1058-1064. doi: 10.7326/M20-6662. Epub 2021 Jun 1. PMID: 34058101.

review and recommendations to help guide their decisions for such measures. We urge Battelle to reconvene this important body to allow it to continue its vital work, and to assign these renal measures for SMP review.

Finally, we note that detailed measure specifications and testing information were not posted until June 5, three weeks *after* the measures were initially released for comment and—importantly—just *one day prior* to the originally disseminated comment deadline date of June 6. Later the same day, without warning or explanation, the comment deadline was abruptly extended to June 25, leaving stakeholders in the position of having to revise comments already prepared for submission. While it is unclear on the P4QM website, it also appears that this may be a limited, “early” (pre-Standing Committee evaluation) comment period. We assume there will also be a longer public comment period after the Standing Committee reviews the measures, but again, this information is not provided. These are significant procedural changes from those of CMS’s prior CBE, NQF, which offered a multi-month continuous comment period for its projects. As we navigate this unprecedented transition between CBEs, we stress the importance of providing a clearly defined consensus development process and detailed project timelines, and we urge the P4QM to make this information readily available to its stakeholders.

Measure-specific comments follow.

### **DELAY IN PROGRESSION OF CHRONIC KIDNEY DISEASE (#3753)**

KCP believes that the goal of delaying progression to ESRD is paramount, and we applaud and support the efforts of CMS and Battelle to address this preventive aspect of kidney care. However, we believe the measure as currently specified will not accurately capture the intended cohort. Below we offer a number of suggestions we believe would help strengthen the measure, but we ultimately believe the proposal for its use is premature and cannot support the measure until there is improvement in Electronic Health Record (EHR) data and coding practices to allow for improved case identification.

#### **Validity**

- **Identification of Stage 4 CKD Cases:** While there was an acceptably high match rate on data element validation, ostensibly suggesting the use of claims to identify denominator cases can achieve the intended measure cohort, we note that inclusion in the denominator only requires a *single* Stage 4 code (N18.4) in a *single* claim during the measurement year. Given the reality that patients may move between CKD stages, this construct may lead to the inadvertent inclusion of CKD Stage 3 patients in the denominator. We believe this reality is reflected in the performance gap demonstrated between analyses of the risk model with and without inclusion of eGFR data; we hypothesize this gap, while small, could be further closed with more rigorous CKD Stage 4 coding requirements. To remedy this issue, KCP recommends the measure should require more than one CKD Stage 4 code documented during the year. Ideally, the appropriate number of codes required would be determined empirically.
- **Lack of eGFR and Albuminuria Laboratory Data:** Likewise, while a conventionally accepted majority agreed the measure can differentiate provider quality, we note that more than a quarter of CMS’s Technical Expert Panel (TEP) members did *not* support the measure’s face validity, largely secondary to concerns about potential cohort misidentification in the absence of eGFR and albuminuria clinical data. We concur that laboratory results are necessary to identify progression of disease and to provide precision in identifying the appropriate patient risk profile for the measure outcome.

The international Kidney Disease Improving Global Outcomes (KDIGO) CKD Evaluation and Management Guideline, as well as the US-specific Kidney Disease Outcomes Quality Initiative (KDOQI) commentary on the CKD guideline both emphasize using eGFR and albuminuria in concert to assess risk and group individuals into risk categories for prognostication and treatment. Current risk equations for kidney failure, such as the Kidney Failure Risk Equation (KFRE) and the CKD Prognosis Consortium equation rely heavily on these two kidney disease markers for risk stratifying among individuals with CKD, achieving c-statistics of ~0.90 in multiple populations worldwide with an

equation including only age, sex, eGFR and albuminuria.<sup>2</sup> Highlighting how impactful eGFR and albuminuria are for risk prediction, for a 70 year-old woman, the 2-year risk of ESRD with an eGFR of 28 mL/min/1.73m<sup>2</sup> and urine albumin to creatinine ratio (UACR) of 10 mg/g is 1.5% when using the KFRE. In contrast, if the eGFR is 17 mL/min/1.73 m<sup>2</sup> and UACR is 750 mg/g, the 2-year risk of ESRD is 31%. Both of these individuals have CKD Stage 4; however, the risk of ESRD is *20-fold higher* in the second individual. This is recognized in clinical practice, where the first individual would be designated as CKD Stage G4A1 and the second as CKD Stage G4A3, clearly highlighting different risk.

The current measure as proposed also may worsen disparities. There are considerable differences in the prevalence of albuminuria by race/ethnicity, with a recent report from the Centers for Disease Control and Prevention Chronic Kidney Disease Surveillance Team demonstrating that more than 13% of non-White individuals with CKD have severely elevated albuminuria (>300 mg/g), compared to 8% of White individuals. In this report, there was better performance on many CKD care process measures among non-White patients than among White patients, contrasting with the known higher risk of kidney failure among non-White patients.<sup>3</sup> This finding emphasizes that improving care processes alone may be inadequate for reducing disparities. Critically, it also highlights the potentially substantial risk differences by ethnicity that need to be accounted for in an equitable quality program, including by incorporation of both albuminuria and eGFR into risk adjustment.

Nephrology clinicians recognize and rely on eGFR and albuminuria to risk stratify and guide treatment decisions, including planning for kidney failure. While we acknowledge that eGFR and albuminuria data are not currently available in such a way that would enable seamless incorporation into a risk adjustment process for a quality metric, implementing any CKD Progression metric without these data and without recognizing the heterogeneity within a CKD stage lacks face validity and is discordant with clinical practice.

This issue is of particular concern in smaller provider groups, wherein there are not a sufficient number of patients to smooth the impact of discrepant claims and clinical data. As above, because of this issue, we cannot support the measure until there is improvement in Electronic Health Record (EHR) data and coding practices to allow for improved case identification.

- **Cancer Diagnosis Exclusions:** The measure excludes patients with metastatic and advanced cancers; however, cases are identified exclusively from ICD-10 codes from an *inpatient* encounter. As such, the measure may not capture all appropriate exclusions, given that some such patients may be managed exclusively in the outpatient setting. KCP thus recommends expanding the exclusion definition to capture both inpatient and outpatient ICD-10 codes for metastatic and advanced cancers.

### Reliability by Provider Size

Importantly, while overall reliability was acceptable at 0.696, results for small practices (<25 cases) were not provided. Given the drop in reliability, from 0.821 when only including larger providers, it is likely that the reliability for these small groups—nearly 1/3 of all nephrology groups—does not meet the established minimum standard of 0.6. Prior trends with other CMS risk-standardized ratio measures support this supposition. To illustrate our point, CMS’s Standardized Transfusion Ratio for Dialysis Facilities (STrR) measure (NQF 2979) was found to have an overall IUR of 0.60; however, the IUR for small facilities (defined by CMS as <=46 patients for the STrR) was only 0.3 (“poor” reliability). Without evidence to the contrary, KCP is concerned that reliability for Measure 3753 is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this

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<sup>2</sup> Tangri N, Grams ME, Levey AS et al. CKD Prognosis Consortium. Multinational assessment of accuracy of equations for predicting risk of kidney failure: A meta-analysis. *JAMA*. 2016 Jan 12;315(2):164-74. doi: 10.1001/jama.2015.18202. Erratum in: *JAMA*. 2016 Feb 23;315(8):822. PMID: 26757465; PMCID: PMC4752167.

<sup>3</sup> Chu CD, Powe NR, McCulloch CE et al. Centers for Disease Control and Prevention Chronic Kidney Disease Surveillance Team. Trends in chronic kidney disease care in the US by race and ethnicity, 2012-2019. *JAMA Netw Open*. 2021 Sep 1;4(9):e2127014. doi: 10.1001/jamanetworkopen.2021.27014. PMID: 34570204; PMCID: PMC8477264.

substantial subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size, and we recommend a small group exclusion be incorporated if reliability is in fact inadequate among such providers.

### Risk Model

- **Albuminuria and eGFR:** As above, eGFR and albuminuria clinical data are necessary for precision in identifying patients' risk profiles for the measure outcome; these clinical laboratory values should thus be included in the measure risk model. Again, this issue is of particular concern in smaller provider groups, wherein there are not a sufficient number of patients to smooth the impact of discrepant claims and clinical data.
- **Social Risk Variables:** While CMS did find the odds of CKD progression are higher among patients who are dual-eligible, Black, have low SES, or reside in an urban county, they noted that the relationship between each variable and the outcome is greatly attenuated in a multivariable model, suggesting clinical risk variables account for most of the risk. Given the minimal impact on provider scores and the risk of masking differential care for patients, social risk factors were not included in the measure's final risk model. KCP shares CMS's concern that risk adjustment can mask real differences in care based on sociodemographic variables; however, we believe that stratification can be an appropriate alternative approach to social risk in some measures; we suggest this approach would be particularly beneficial when assessing progression of kidney disease. CKD progression is more rapid for racial and ethnic minority groups as compared to whites. Stark socioeconomic disparities in outcomes for dialysis patients exist, and vary by race, place of residence, and treatment facility. Disparities in access to living kidney donation may also be driven primarily by the socioeconomic status of the donor as opposed to recipient factors.<sup>4</sup> Given these well-established inequities in CKD burden, care, and outcomes, we urge CMS to consider measure stratification by known social risk factors to allow providers and other healthcare stakeholders to identify and prioritize differences in care and outcomes across different sociodemographic groups and to develop and implement equity-focused practices to better address disparities.

### Attribution

- **Late Referrals:** We note that there is oftentimes a lack of appropriate care coordination between providers, such that many patients are not referred for nephrology care until dialysis is imminent. Attribution of progression to the nephrologist in such instances does not provide an accurate representation of the care provided by that physician/group and is both inappropriate and unfair. This concern could be remedied by requiring more patient nephrology encounters than the currently proposed two, although the "appropriate" number has not been identified and would need to be clearly and transparently delineated.
- **Nephrology Group Identification:** Additional detail is needed on how a nephrology group is identified for the purposes of this measure. While submitted materials indicate measured entities are any clinician group billing for nephrology services to Medicare FFS patients, grouped by taxpayer identification number (TIN), we note that many nephrologists/groups provide both Internal Medicine and Nephrology care. The point at which a patient receiving care from such a provider transitions from primary care to specialized care is not always clear, which may further compromise accurate cohort identification.

### RISK-STANDARDIZED MORTALITY RATIO FOR LATE-STAGE CKD AND ESRD (#3754)

KCP believes mortality is an important outcome to measure, but has a number of concerns with the RSMR

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<sup>4</sup> Crews DC et al. Disparities in the burden, outcomes, and care of chronic kidney disease. *Curr Opin Nephrol Hypertens*. 2014;23(3):298-305.

## Validity

- **Identification of Stage 4 and 5 CKD Cases:** While there was an acceptably high match rate on data element validation, ostensibly suggesting the use of claims to identify denominator cases can achieve the intended measure cohort, we note again here that inclusion in the denominator only requires a *single* Stage 4 (N18.4) or Stage 5 (N18.5) code in a *single* claim during the measurement year. Given the reality that patients may move between CKD stages, this construct may lead to the inadvertent inclusion of Stage 3 patients in the denominator. To remedy this issue, KCP recommends the measure should require more than one Stage 4 or 5 code documented during the year. Ideally, the appropriate number of codes required would be determined empirically.
- **Lack of eGFR and Albuminuria Laboratory Data:** While Face Validity was apparently not assessed with the RSMR, as with Measure #3753, KCP again has concerns about potential cohort misidentification in the absence of eGFR and albuminuria clinical laboratory data. Again, laboratory results are necessary to identify progression of disease and to provide precision in identifying the appropriate patient risk profile for the measure outcome.

The international Kidney Disease Improving Global Outcomes (KDIGO) CKD Evaluation and Management Guideline, as well as the US-specific Kidney Disease Outcomes Quality Initiative (KDOQI) commentary on the CKD guideline both emphasize using eGFR and albuminuria in concert to assess risk and group individuals into risk categories for prognostication and treatment. Current risk equations for kidney failure, such as the Kidney Failure Risk Equation (KFRE) and the CKD Prognosis Consortium equation rely heavily on these two kidney disease markers for risk stratifying among individuals with CKD, achieving c-statistics of ~0.90 in multiple populations worldwide with an equation including only age, sex, eGFR and albuminuria.<sup>5</sup> Highlighting how impactful eGFR and albuminuria are for risk prediction, for a 70 year-old woman, the 2-year risk of ESRD with an eGFR of 28 mL/min/1.73m<sup>2</sup> and urine albumin to creatinine ratio (UACR) of 10 mg/g is 1.5% when using the KFRE. In contrast, if the eGFR is 17 mL/min/1.73 m<sup>2</sup> and UACR is 750 mg/g, the 2-year risk of ESRD is 31%. Both of these individuals have CKD Stage 4; however, the risk of ESRD is *20-fold higher* in the second individual. This is recognized in clinical practice, where the first individual would be designated as CKD Stage G4A1 and the second as CKD Stage G4A3, clearly highlighting different risk.

The current measure as proposed also may worsen disparities. There are considerable differences in the prevalence of albuminuria by race/ethnicity, with a recent report from the Centers for Disease Control and Prevention Chronic Kidney Disease Surveillance Team demonstrating that more than 13% of non-White individuals with CKD have severely elevated albuminuria (>300 mg/g), compared to 8% of White individuals. In this report, there was better performance on many CKD care process measures among non-White patients than among White patients, contrasting with the known higher risk of kidney failure among non-White patients.<sup>6</sup> This finding emphasizes that improving care processes alone may be inadequate for reducing disparities. Critically, it also highlights the potentially substantial risk differences by ethnicity that need to be accounted for in an equitable quality program, including by incorporation of both albuminuria and eGFR into risk adjustment.

Nephrology clinicians recognize and rely on eGFR and albuminuria to risk stratify and guide treatment decisions, including planning for kidney failure. While we acknowledge that eGFR and albuminuria data are not currently available in such a way that would enable seamless incorporation into a risk adjustment process for a quality metric, implementing any CKD Progression metric without these

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<sup>5</sup> Tangri N, Grams ME, Levey AS et al. CKD Prognosis Consortium. Multinational assessment of accuracy of equations for predicting risk of kidney failure: A meta-analysis. *JAMA*. 2016 Jan 12;315(2):164-74. doi: 10.1001/jama.2015.18202. Erratum in: *JAMA*. 2016 Feb 23;315(8):822. PMID: 26757465; PMCID: PMC4752167.

<sup>6</sup> Chu CD, Powe NR, McCulloch CE et al. Centers for Disease Control and Prevention Chronic Kidney Disease Surveillance Team. Trends in chronic kidney disease care in the US by race and ethnicity, 2012-2019. *JAMA Netw Open*. 2021 Sep 1;4(9):e2127014. doi: 10.1001/jamanetworkopen.2021.27014. PMID: 34570204; PMCID: PMC8477264.

data and without recognizing the heterogeneity within a CKD stage lacks face validity and is discordant with clinical practice.

This issue is of particular concern in smaller provider groups, wherein there are not a sufficient number of patients to smooth the impact of discrepant claims and clinical data. As with Measure 3753, because of this issue, we cannot support the measure until there is improvement in Electronic Health Record (EHR) data and coding practices to allow for improved case identification.

## Exclusions

- **Cancer Diagnosis Exclusions:** The measure excludes patients with metastatic and advanced cancers; however, cases are identified exclusively from ICD-10 codes from an *inpatient* encounter. As such, the measure may not capture all appropriate exclusions, given that some such patients may be managed exclusively in the outpatient setting. KCP thus recommends expanding the exclusion definition to capture both inpatient and outpatient ICD-10 codes for metastatic and advanced cancers.
- **Palliative Care:** While hospice enrollment is a measure exclusion, this does not account for the significant number of patients who opt out of dialysis in favor of palliative care. We recognize there is currently no sufficiently valid means of reliably capturing this data point, but we note that patients opting for this treatment approach will likely increase in the coming years—particularly with an increased emphasis on patients’ life goals, as is the intent of the next measure. As such, we can expect that this issue will increasingly contribute to an inaccurate cohort capture over time. More importantly, the failure to account for patient choice to value quality over longevity contrasts with the goal of a patient-centered quality metric by incentivizing more intensive care over goal-concordant care. A metric spanning advanced CKD and dialysis needs to incorporate patient choice for comprehensive non-dialysis, non-hospice medical care. Again, eventual improvement in EHR data and coding practices would presumably allow for improved case identification in this regard, as well.

## Reliability by Provider Size

Overall reliability was sufficient at 0.623, but results for small practices (<25 cases) were again not provided. Given the drop in reliability from 0.742 when small providers were excluded, it is likely that the reliability for these small groups—nearly 20 percent of all nephrology groups—does not meet the established minimum standard of 0.6. As illustrated above, prior trends with other CMS risk-standardized ratio measures support this supposition. Without evidence to the contrary, KCP is concerned that reliability for Measure 3754 is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this substantial subset of providers. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size, and we recommend a small group exclusion be incorporated if reliability is in fact inadequate among such providers.

## Social Risk Variables

CMS found no statistically significant relationship between dual eligibility, low AHRQ SES, race, and urbanicity and measure scores among nephrology practices with the highest proportion of patients with these social risk factors. Because of the minimal impact on provider scores and the risk of masking differential care for patients, social risk factors were not included in the measure’s final risk model. KCP shares CMS’s concern that risk adjustment can mask real differences in care based on sociodemographic variables; however, we believe that stratification can be an appropriate alternative approach to social risk in some measures. Given well-established variations in mortality rates across sociodemographic groups,<sup>7</sup> we urge CMS to consider measure stratification by known social risk factors to allow providers and other

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<sup>7</sup> United States Renal Data System. [2022 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. (See [Figure 6.1b](#).)

healthcare stakeholders to identify differences in care and outcomes and to develop and implement equity-focused practices to better address disparities.

### All-Cause Construct

Finally, KCP strongly objects to the all-cause construct of the RSMR, believing it is too expansive in scope and will unfairly penalize clinicians and groups for outcomes beyond their control or sphere of influence. We note that the corollary facility-level mortality measure specifically excludes deaths due to street drugs or accidents unrelated to treatment; we urge CMS to revise Measure 3754 to incorporate these same numerator case exclusions.

### Attribution

- **Late Referrals:** We note that there is oftentimes a lack of appropriate care coordination between providers, such that many patients are not referred for nephrology care in a timely manner. Attribution of patient mortality to the nephrologist in such instances does not provide an accurate representation of the care provided by that physician/group and is both inappropriate and unfair. This concern could be remedied by requiring more patient nephrology encounters than the currently proposed two, although the “appropriate” number has not been identified and would need to be clearly and transparently delineated.
- **Nephrology Group Identification:** Additional detail is needed on how a nephrology group is identified for the purposes of this measure. While submitted materials indicate measured entities are any clinician group billing for nephrology services to Medicare FFS patients, grouped by taxpayer identification number (TIN), we note that many nephrologists/groups provide both Internal Medicine and Nephrology care. The point at which a patient receiving care from such a provider transitions from primary care to specialized care is not always clear, which may further compromise accurate cohort identification.

### ESRD DIALYSIS PATIENT LIFE GOALS SURVEY (#3742)

KCP appreciates the underlying premise of the "Dialysis Facility-Level ESRD Dialysis Patient Life Goals Survey" (PaLS) measure, and we applaud CMS for its recognition of this important aspect of patient quality of life. However, we have a number of serious concerns with the measure as presented on the P4QM website that would need to be addressed before we are able adequately review the measure or offer our support of its use in the penalty based ESRD QIP.

We note that CMS is proposing a facility-level process measure assessing the percent of eligible patients in a given dialysis facility that completed at least one scorable item of the survey. However, only patient-level testing data on the survey instrument itself was provided; there was no information provided on the facility-level process measure being proposed for use. All information provided with the submission materials is on the survey t-score, based on the data collected during testing of the instrument—but the t-score is ***“currently not part of the calculation for process measure being proposed.”*** CMS itself notes in the measure specifications that prior to implementation at the dialysis facility level, the response rate will need to be calculated *at* the dialysis facility level; it is unclear why this was not done prior to submission. Detailed information (performance scores, reliability, validity) for the performance metric being proposed, *as specified*, is a foundational component of the consensus development and endorsement processes. An assessment of the PaLS is not feasible in the absence of this information.

At NQF, a critical assessment of survey instruments’ methodologic and psychometric properties has been a required component of the Scientific Methods Panel (SMP) review. It remains unclear if the SMP will continue its work at Battelle to provide such a critical assessment; nevertheless, KCP’s support of the measure is necessarily contingent upon a proper review of the survey’s methodologic and psychometric properties by the SMP or an equivalent body at Battelle.

We also note that several of our patient and patient advocate members have raised concerns about the appropriateness of tying provider reimbursement to required questioning of patients on information so personal as life goals. These members echoed patient reservations detailed by our sister organization, the Kidney Care Quality Alliance (KCQA), in its 2017 Expert Panel Report on [Patient-Reported Outcomes for ESRD Patients: A Framework and Priorities for Measurement](#), again highlighting the mistrust some patients harbor with patient satisfaction and quality-of-life surveys for fear of potential differential treatment based on responses. Yet, of course, patients must be comfortable answering honestly for such measures to drive improvements in care and quality. As such, we do not believe the penalty-based ESRD QIP is the appropriate quality program for use of the PaLS measure. While KCP unequivocally supports empowering patients to achieve their vision of a high-quality life, there are other measures that more appropriately address the *clinical* aspects of achieving *health-related* QOL goals.

KCP also has concerns with the lack of any detail provided on potential implementation issues, including operational issues such as the anticipated administrative burden associated with administering the survey. Likewise, patients' increasing survey fatigue and potential privacy concerns with the PaLS are very real threats to validity that remain unaddressed. Third, the denominator currently includes only individuals able to "read and understand English", excluding a wide swath of the dialysis population and potentially exacerbating disparities. Finally, while considerable evidence highlighting the importance of patient life goals is presented in the submission materials, an association between the administration of a life goals survey with subsequent improved outcomes in the dialysis facility setting has not been demonstrated.

We look forward to a detailed discussion on these issues by the Standing Committee.

KCP again thanks you for the opportunity to comment on this important work. If you have any questions, please do not hesitate to contact Lisa McGonigal, MD, MPH ([lmcgon@msn.com](mailto:lmcgon@msn.com)).

Sincerely,

Kidney Care Partners

Akebia Therapeutics, Inc.  
American Kidney Fund, Inc.  
American Nephrology Nurses Association  
American Society of Nephrology  
American Society of Pediatric Nephrology  
Ardelyx  
AstraZeneca  
Atlantic Dialysis Management Services, LLC  
Baxter International, Inc.  
Cara Therapeutics, Inc.  
Centers for Dialysis Care  
CorMedix Inc.  
CSL Vifor  
DaVita, Inc.  
Dialysis Patient Citizens, Inc.  
Fresenius Medical Care



Greenfield Health Systems  
Kidney Care Council  
North American Transplant Coordinators Organization  
Nephrology Nursing Certification Commission  
Renal Healthcare Association  
Renal Physicians Association  
Renal Support Network  
Rogosin Institute  
Satellite Healthcare, Inc.  
U.S. Renal Care, Inc.  
Unicycive Therapeutics, Inc.