



April 30, 2023

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

RE: Renal Project Fall 2022 Cycle Final 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. We commend Battelle and the Partnership for Quality Measurement for undertaking this important work and offer comment on the three new measures under review within the Renal Fall 2022 Project:

- **NQF 3722: Home Dialysis Rate**
- **NQF 3725: Home Dialysis Retention**
- **NQF 3719: Prevalent Standardized Waitlist Ratio**

HOME DIALYSIS RATE (MEASURE 3722, Kidney Care Quality Alliance [KCQA])

HOME DIALYSIS RETENTION (MEASURE 3725, KCQA)

KCP fully supports endorsement of KCQA's Home Dialysis Measure Set and thus strongly disagrees with the Renal Standing Committee's decision against these important measures. The Committee's recommendation on these measures is deeply problematic and fundamentally undercuts NQF's methodological and scientifically rigorous endorsement process.

As illustrated by the developer, peritoneal dialysis (PD) yields similar short- and long-term survival to in-center hemodialysis (HD) for individuals with ESKD,¹ PD has been found to enhance patient autonomy and quality of life, is associated with preservation of residual kidney function, and is significantly less expensive to deliver than in-center dialysis.^{2,3} Likewise, frequent home hemodialysis (HHD) is associated with improved blood pressure control and regression of left ventricular hypertrophy, shorter recovery time from dialysis treatments, normalization of phosphate levels, improved pregnancy outcomes, and better health-related quality of life.⁴ Moreover, with more frequent therapies, both PD and HHD eliminate the prolonged two-day interdialytic gap that can adversely affect outcomes.⁵ Yet despite the

¹ Mehrotra R, Devuyst O, Davies SJ, Johnson DW. The current state of peritoneal dialysis. *J Am Soc Nephrol.* 2016;27:3238-3252.

² Saran R, Robinson B, Abbott KC, et al. US Renal Data System 2017 Annual Data Report: Epidemiology of kidney disease in the United States. *Am J Kidney Dis.* 2018;71(3)(suppl 1):A7-A8.

³ Ishani A, Slinin Y, Greer N, et al. VA evidence-based synthesis program reports. In: *Comparative Effectiveness of Home-Based Kidney Dialysis Versus In-Center or Other Outpatient Kidney Dialysis Locations - A Systematic Review.* Washington, DC: Department of Veterans Affairs (US); 2015.

⁴ Tennankore K, Nadeau-Fredette AC, Chan CT. Intensified home hemodialysis: Clinical benefits, risks and target populations. *Nephrol Dial Transplant.* 2014;29(7):1342-1349.

⁵ Foley RN, Gilbertson DT, Murray T, Collins AJ. Long interdialytic interval and mortality among patients receiving hemodialysis. *N Engl J Med.* 2011;365(12):1099-1107.

favorable impact on clinical, patient-reported, and fiscal outcomes, home modalities are still used at substantially lower rates in the U.S. than in other developed nations,⁶ hovering at only around 15%.⁷

Accordingly, increasing home dialysis is a major objective of the new ESRD Treatment Choices (ETC) Payment Model and, as such, the Centers for Medicare and Medicaid Services (CMS) has identified home dialysis utilization as one of the performance metrics to be used within this program.⁸ Yet, in an unprecedented departure from protocol for measures used in penalty-based programs, because of the absence of valid, reliable, CBE-endorsed home dialysis measures, the Agency is currently relying on an unvetted, untested metric for which stakeholders in the renal community were not provided an opportunity for review or public comment.

The KCQA Home Dialysis Measures were developed specifically to provide CMS the rigorously vetted and empirically tested measures it needs for the program. Testing encompassed 543,115 patients; 4,937,405 patient-months; 5,792 dialysis facilities; and 295 Hospital Referral Regions across the United States. They were developed by an eight-member [Technical Expert Home Dialysis Workgroup](#) and a broad-based fifteen-member [Steering Committee](#), both consisting of nephrologists, nurses, patients/advocates, epidemiologists, dialysis facility administrators, and researchers. Both measures enjoy the strong support of the renal community, with near-unanimous endorsement from KCQA's thirty [Member Organizations](#) and overwhelming approval from an unaffiliated 35-member Face Validity Panel—of which nearly half, notably, were ESRD patients (in-center and home dialysis and post-transplant). Within NQF, the Scientific Methods Panel had unanimously approved both measures as scientifically sound (reliable and valid) and feasible, and preliminary Renal Standing Committee and NQF staff reviews were overwhelmingly supportive of both measures.

We are thus confused and dismayed that despite all of the above, as well as the NQF Renal Standing Committee's acknowledgement of the at least equivalent clinical outcomes and the superior patient-reported and fiscal outcomes with home modalities, one Committee member was successful in persuading his colleagues that the lack of *randomized controlled trials (RCTs)*, in particular, that definitively establish clinical superiority of home over in-center dialysis was a sufficient rationale to recommend against endorsement. We note that NQF's own Evidence Algorithm does not require RCTs for a measure to pass the Evidence Criterion; the application of such academic, controlled studies is often simply not feasible—or ethical—in real-world clinical settings. And, appropriately, both measures did overwhelmingly pass the Standing Committee's preliminary Evidence review, in which it agreed with “high certainty” that the submitted evidence indicates that the potential benefits of the measures clearly outweigh potential risks. We thus assert that in reversing its initial position, the Committee did not adhere to the Algorithm in its final review of the measures, succumbing to the unfeasible, extraordinary, and inappropriate RCT standard demanded by one outspoken Committee member.

Of note, the aforementioned Committee member's primary concern was that endorsement of the KCQA measures would implicitly denote NQF's support of home over in-center dialysis and would thus promote uptake of home modalities—which, again, he deemed inappropriate without RCT-based evidence of its clinical superiority. However, *home dialysis utilization measurement is already underway*, making this a moot issue. The ETC model, which provides significant financial incentives—and penalties—to improve home dialysis utilization, is currently using an untested, unvetted metric because of the absence of a CBE-endorsed measure. KCQA convened specifically to address this measurement gap and has successfully

⁶ Chan CT, Wallace E, Golper TA, Rosner MH, et al. Exploring barriers and potential solutions in home dialysis: An NKF-KDOQI Conference Outcomes Report. *Am J Kidney Dis*. 2018 Dec 10. pii: S0272-6386(18)31060-6.

⁷ 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. (See [Figure 2.1a](#).)

⁸ CMS Innovation Center (CMMI). [ESRD Treatment Choices \(ETC\) Model](#). Last updated 09/14/2022.

developed meaningful home dialysis measures that *fully* meet NQF’s *established* endorsement criteria. Holding the measures to standards that exceed those criteria does nothing to address the Committee member’s concern of promoting home uptake; it merely deprives the renal community of the tools it desperately needs in this regard—CBE-endorsed measures that have been rigorously tested and demonstrated as reliable, valid, and meaningful, and that enjoy broad and strong community support.

For all of the above reasons, KCP strongly supports the KCQA Home Dialysis Measure set and urges the Renal Standing Committee to revise its improper recommendation against the measures.

MEASURE 3719: PREVALENT STANDARDIZED WAITLIST RATIO (CMS)

KCP concurs with the Renal Standing Committee’s recommendation against Measure 3719. KCP recognizes the tremendous importance of improving transplantation rates for patients with ESRD, but does not support the attribution of successful or unsuccessful waitlisting to individual practitioners or group practices and thus cannot support this measure. KCP believes that while referral to a transplant center and initiation or even completion of the waitlist evaluation process might be appropriate measures for these levels of analysis that could be used in CMS’s quality programs, the newly proposed clinician/group level Prevalent Standardized Waitlist Ratio (PSWR) measure is not. Waitlisting per se is a decision made by the transplant center and is beyond the locus of control of the providers targeted in this measure. In reviewing the details of the measure, we offer the following comments:

- **Attribution.** As above, we strongly object to attributing successful/unsuccessful placement on a transplant waitlist to individual clinicians or group practices and believe this is a fatal structural flaw with the measure. The transplant center decides whether a patient is placed on a waitlist, not the practitioner or group practice. KCP patient members who are transplant recipients have noted there are many obstacles and delays in the evaluation process with multiple parties that have nothing to do with the treating nephrologist or group. For instance, one patient noted their private pay insurance changed the locations where they could be evaluated for transplant eligibility on multiple occasions, repeatedly interrupting the process mid-stream. Penalizing a clinician/group practice each month through the PSWR for these or other delays is not only inappropriate; it is fundamentally misaligned with NQF’s first “Attribution Model Guiding Principle” that measures’ attribution models should fairly and accurately assign accountability.⁹ KCP emphasizes our commitment to improving transplantation access, but we believe other measures with an appropriate sphere of control should be pursued. For example, our sister organization, the Kidney Care Quality Alliance (KCQA), has developed a dialysis facility-level Transplant Access Measure Set that will be submitted to NQF for endorsement consideration later this year. The set pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years. Because the KCQA waitlisting measure denominator is limited to those patients specifically identified as appropriate transplant candidates and deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than less precise metrics like the PSWR; this construct will also provide a counterbalance to the referral measure, curbing the tendency to indiscriminately refer patients who are not appropriate transplant candidates, preventing unnecessary patient and transplant center burden. The same approach could be applied at the clinician/group level.
- **Variation in Transplant Center Eligibility Criteria.** We also note that criteria indicating a patient is “not eligible” for transplantation can differ by geographic location. For instance, one center might require evidence of an absence of chronic osteomyelitis, infection, heart failure, etc., while

⁹ NQF. Attribution: Principles and Approaches Final Report. December 2016.
<http://www.qualityforum.org/ProjectDescription.aspx?projectID=80808>.

another may apply eligibility exclusions differently or have additional or 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 waitlisting.

- **Measure Reliability.** Finally, the overall IUR of the PSWR is 0.56, interpreted as “questionable” reliability by statistical convention.¹⁰ Thus nearly half of the observed variation in the measure could be attributed to random noise rather than true performance differences between providers. Additionally, as reliability statistics were not stratified by facility size, we are unable to discern how widely reliability varies across the spectrum of practitioner and group practice sizes. As has been the case with other CMS standardized ratio measures, we are concerned that the reliability for small providers might be substantially lower than the overall IURs. 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 PSWR reliability is similarly lower for small groups, effectively rendering the metric meaningless for use in performance measurement in this substantial subset of providers. Notably, the many such providers that treat small rural or low-income communities could be disproportionately impacted, resulting in the imposition of random and specious penalties on the most financially vulnerable clinician groups treating the most socially and medically disadvantaged patients. KCP believes it is incumbent on CMS to demonstrate reliability for all providers by stratifying data by practice size.

KCP again thanks you for the opportunity to comment on these measures. If you have any questions, please do not hesitate to contact Lisa McGonigal, MD, MPH (lmcgon@msn.com).

Sincerely,

Kidney Care Partners Chairman

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

John Butler

¹⁰ Landis J, Koch G. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33:159-174.