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The Honorable Liz Fowler  
Deputy Administrator  
Director  
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Dear Dr. Fleisher and Deputy Administrator Fowler,

I am writing on behalf of Kidney Care Partners (KCP) to share an update on the community's consensus-based development of two measure sets in the area of home dialysis and transplant that we encourage the Centers for Medicare & Medicaid Services (CMS) to adopt in the End Stage Renal Disease (ESRD) Quality Incentive Program (QIP), the ESRD Treatment Choices (ETC) model, and the Kidney Care Choices (KCC) model. The Kidney Care Quality Alliance (KCQA) developed both measure sets to support the community and CMS' efforts to improve access to home dialysis modalities and transplant. As the primary non-governmental dialysis facility measure developer for the kidney care community, KCQA is committed to eliminating healthcare inequities for individuals living with kidney disease.

This letter provides an overview of the measures and the evidence for them. We would welcome the opportunity to meet with your teams to talk about the potential next steps for incorporating these measures into the ESRD quality programs and kidney care innovation models.

## **I. Home Dialysis**

KCP encourages CMS to adopt in the CMMI ETC and KCC models, as well as in the ESRD QIP, the KCQA's home dialysis measure set, which includes a home dialysis rate and a home dialysis retention measure. KCP plans to submit the measures to the Measure Application Partnership (MAP) for addition on the Measures Under Consideration (MUC) list before the May deadline.

### **A. Background on the KCQA Home Dialysis Measure Set**

The KCQA sought to develop home dialysis measures to help address the health inequity associated with the selection of home dialysis modalities. Currently, nearly 45% of dialysis patients are Black or Brown, but only about 11% of home dialysis patients are included in these demographic groups. The Biden-Harris Administration and CMS have prioritized improving access to home care options and eliminating such related health

disparities, deploying the ESRD Treatment Choices (ETC) model in January 2021. These home dialysis measures were developed by KCQA specifically to support the ETC program. KCQA submitted the measure set to NQF for endorsement within the Renal Fall 2022 Project Cycle. In October 2022, the Scientific Methods Panel (SMP) determined they met the validity and reliability requirements for measure endorsement.<sup>1</sup> The Renal Standing Committee, however, indicated that due to the lack of randomized controlled trials demonstrating superior clinical outcomes with home dialysis when compared to in-center hemodialysis (HD), there was insufficient evidence to support the adoption of any measure to incentivize the adoption of home dialysis modalities. Clearly, KCP – like the Biden-Harris Administration – disagrees with any suggestion that home dialysis does not provide high quality care to those individuals who require dialysis or that home dialysis does not provide better outcomes for many patients. The clinical literature also contradicts the conclusion of the NQF Renal Standing Committee. Given that the lack of endorsement comes from an academic-centered rather than a patient-centered approach to measure development, KCP believes that CMS should move forward with adopting these measures for its ESRD quality programs.

## **B. Rationale for the KCQA Home Dialysis Measure Set**

Dialysis modality selection impacts both clinical and patient-reported outcomes.<sup>2</sup> While peritoneal dialysis (PD) yields similar short- and long-term survival to in-center HD for individuals with ESRD,<sup>3</sup> PD enhances patient autonomy and quality of life, is associated with preservation of residual kidney function, and is less expensive to deliver than in-center dialysis.<sup>4</sup> 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, and improved pregnancy outcomes, and better health-related quality of life.<sup>5</sup> Moreover, with more frequent therapies, both PD and HHD eliminate the prolonged two-day interdialytic gap that can adversely affect outcomes.<sup>6</sup> Nevertheless, home modalities are still used at

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<sup>1</sup> See NQF's Scientific Methods Panel October 25, 2022 Meeting Summary at [https://www.qualityforum.org/Measuring\\_Performance/Scientific\\_Methods\\_Panel/Meetings/2022\\_Scientific\\_Methods\\_Panel\\_Meetings.aspx](https://www.qualityforum.org/Measuring_Performance/Scientific_Methods_Panel/Meetings/2022_Scientific_Methods_Panel_Meetings.aspx).

<sup>2</sup>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.

<sup>3</sup>Mehrotra R, Devuyst O, Davies SJ, Johnson DW. The current state of peritoneal dialysis. *J Am Soc Nephrol.* 2016;27:3238-3252.

<sup>4</sup>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; 4. 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.

<sup>5</sup>Tennankore K, Nadeau-Fredette AC, Chan CT. Intensified home hemodialysis: Clinical benefits, risks and target populations. *Nephrol Dial Transplant.* 2014;29(7):1342-1349.

<sup>6</sup>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.

substantially lower rates in the U.S. than in other developed nations,<sup>7</sup> hovering at only around 15%.<sup>8</sup>

Accordingly, increasing home dialysis is a major objective of the Biden-Harris Administration, as it has been in previous administrations as well. ESRD Treatment Choices (ETC) Payment Model launched by CMS in January 2021<sup>9</sup> identifies home dialysis utilization as one of the central performance metrics.<sup>10</sup> The KCQA Home Dialysis Measure Set (Home Dialysis Rate [NQF 3722] and Home Dialysis Retention [NQF 3725]) was conceptualized and developed to allow CMS not only to measure the rate of adoption of home dialysis modalities, but also the continued use of the modality after a specified period of time.

The **Home Dialysis Rate Measure**<sup>11</sup> assesses the utilization of home dialysis modalities (peritoneal and home hemodialysis) among all patients assigned to a given dialysis facility and/or Hospital Referral Region (HRR)<sup>12</sup> within the given measurement year. The measure is intended to incentivize prescription of and preparation for home modalities for all clinically appropriate patients, in accordance with patient preference. Specifically, the Home Dialysis Rate Measure will incentivize the facility/HRR to first identify appropriate home dialysis candidates among eligible<sup>13</sup> in-center hemodialysis patients, and to then implement appropriate process interventions (e.g., effective education, patient preparation/training/ support) to increase both home dialysis uptake and retention among those candidates.

The KCQA Home Dialysis Rate Measure can stand alone; however, we recommend it be paired with the accompanying KCQA **Home Dialysis Retention Measure**<sup>14</sup> for optimal results. Paired together, the KCQA’s “Home Dialysis Measure Set” seeks to promote steady, deliberate performance improvement over time by addressing *both* sides of the home dialysis utilization equation—uptake and retention. The set pairs a “core” Home Dialysis Rate Measure with a “guardrail” Home Dialysis Retention Measure, intended to counterbalance the unopposed incentivization of home prescription that might occur if a

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<sup>7</sup>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.

<sup>8</sup>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.)

<sup>9</sup>CMS Innovation Center (CMMI). ESRD Treatment Choices (ETC) Model. Last updated 09/14/2022.

<sup>10</sup>Consistent with CMS’s approach within the ETC Model, in recognition of the structure of the dialysis market, if a company (dialysis organization) owns multiple facilities in a given Hospital Referral Region (HRR), it would report an aggregated score for all facilities located within the HRR owned by the company.

<sup>11</sup>See Appendix A for the measure specifications.

<sup>12</sup>Patients not meeting any of the exclusion criteria in the measurement month.

<sup>13</sup>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 2.11.)

<sup>14</sup>See Appendix B for the measure specifications.

rate measure were implemented alone, minimizing the potential adverse consequences of unchecked home dialysis growth. An incentive-based measurement program that creates significant financial incentives to improve home dialysis utilization could have the unintended consequence of patients not being able to sustain home dialysis beyond the first few months after initiation. Incentivizing a rapid rise in the use of home dialysis in the absence of safeguards and a sufficiently robust infrastructure to support such growth could lead to increased technique failure rates. Adoption of the Home Dialysis Retention Measure will incentivize the facility to implement process interventions (e.g., effective modality education, appropriate patient preparation/training/support) to improve home dialysis retention among patients who have selected and commenced a home modality. The retention measure will also allow providers to more readily assess the success of their efforts to create a *sustainable* home program through appropriate patient education, preparation, and support, and to apply targeted quality improvement interventions as needed.

The testing data are available in Appendix C.

## **II. Transplant**

KCP continues 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 the 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. KCP has shared several recommendations with CMS about policy modifications to better support individuals with kidney failure accessing a transplant, which we outlined in a [2022 letter](#) to the Secretary of Health and Human Services. [Additional transplant policy recommendations](#) are on the KCP's website as well. In addition to these broader system reforms, KCP has supported the work of the KCQA's highly renowned transplant physicians and patient expert panel to develop a set of transplant measures that could be used to track facility performance and inform patient/caregiver decision-making. The KCQA expert panel and Steering Committee believed pairing a referral measure with a well-constructed "counterbalancing" metric will be expected to effectively curb any potential tendency toward "over-referring" that could overwhelm the transplant waitlisting system.

KCP and KCQA have long supported the concept of a dialysis facility-level transplant measure, but believe that such a measure must fall firmly within the realm of the facility's control and be amenable to intervention by the facility — particularly when used in penalty-based payment programs. The three existing dialysis facility-level transplant-related measures put forth by CMS — the Percentage of Prevalent Patients Waitlisted (PPPW), Standardized Waitlist Ratio (SWR), and the ETC Model Transplant Rate Metric — do not meet this "actionability" criterion. Transplant evaluation practices and decisions vary considerably by transplant center, such that dialysis facilities have little control over what patients are ultimately waitlisted or transplanted. Additionally, the SWR and PPPW

have both been empirically demonstrated as lacking statistical validity, confirming that these measures don't provide an accurate assessment of dialysis facility performance — again, likely a reflection of facilities' inability to impact which patients are ultimately waitlisted by transplant centers. Finally, because the ETC metric has never been formally specified, empirically tested, or submitted to NQF for evaluation, it is unclear how the measure will perform or if the results will provide a reliable or valid representation of performance.

The KCQA transplant measure set includes a Transplant Waitlisting Plus Referral Measure<sup>15</sup> that is the percent of all 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<sup>16</sup> 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. 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 using the Percentage of Prevalent Patients Waitlisted (PPPW) measure.

We, like CMS, are interested in pursuing a dialysis facility referral-based metric and recognize that although most dialysis facilities are tracking and documenting referrals internally, referral data are not currently collected nationally, creating challenges when looking to develop such a measure. Effectively, the KCQA measure to not only specifies a novel performance measure set for use in the federal ESRD programs that we believe (based on initial testing with one of the large dialysis organization) will be shown to be valid, reliable, meaningful, and community-supported, but also defines, expedites, and facilitates the creation and collection of this important data element.

We also believe that this measure set is necessary to begin addressing the very real health disparities at the core of CMS' efforts to increase kidney transplants. The disparities in waitlisting are pervasive and well-documented, as we noted in our comment letter last year. 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 and the CMMI models that target the actions dialysis facilities take (or do not take) to promote transplant. Individuals who

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<sup>15</sup>See Appendix D for the measure specifications.

<sup>16</sup>See Appendix E for the measure specifications.

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require dialysis and want to select facilities that have “better” performance cannot obtain the information they need from the PPPW measure.

KCP supports adding this measure set to the ESRD QIP and CMMI models and would welcome the chance to partner with CMS in moving forward with these measures.

### **III. Conclusion**

On behalf of KCP, as well as the experts who participated in the KCQA measure development initiative, I want to thank you for considering our request to include these home dialysis and transplant quality performance measures into Medicare’s ESRD program and the kidney care models. Please do not hesitate to reach out to our counsel in Washington, Kathy Lester, if you have any questions. She will also follow-up with you to schedule a virtual meeting. She can be reached at [klester@lesterhealthlaw.com](mailto:klester@lesterhealthlaw.com) or 202-534-1773.

Sincerely,



John Butler  
Chairman

cc: Jean Moody-Williams, Deputy Director  
Shari M. Ling, M.D., Deputy CMS Chief Medical Officer  
Michelle Schreiber, M.D., Deputy Director for Quality & Value; Director Quality Measurement & Value-Based Incentives Group  
Tamyra Garcia, Deputy Director Quality Measurement & Value-Based Incentives Group  
Reid Kiser, Director, Division of Quality Measurement  
Vinitha Meyyur, Deputy Director, Division of Quality Measurement  
Kathleen Blackwell, Center for Medicare & Medicaid Innovation

**Appendix: KCP Members**

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.  
DialyzeDirect  
Fresenius Medical Care North America  
GlaxoSmithKline  
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.

## **Appendix A: KCQA Home Dialysis Rate Measure Specifications**

**Description:** Percent of all dialysis patient-months in the measurement year in which the patient was dialyzing via a home dialysis modality.

**Numerator Statement:** Patient-months from the denominator in which the patient was dialyzing via a home modality (peritoneal dialysis and/or home hemodialysis) as of the final dialysis treatment of the given measurement month.

**Denominator Statement:** All dialysis patient-months (in-center and/or home) attributed to the dialysis facility (or aggregate HRR unit) during the measurement year.

**Denominator Exclusions:** The following exclusions are applied to the denominator:

1. Patient-months in which the patient was admitted to the facility to which they are attributed for <30 days as of the final day of the measurement month.
2. Patient-months in which the patient is receiving dialysis for AKI only at any time in the measurement month.
3. Patient-months in which the patient is enrolled in hospice at any time in the measurement month.
4. Patient-months in which the patient is residing in a nursing home or other LTCF at any time in the measurement month.
5. Patient-months in which the patient was discharged from the facility secondary to transplant, death, discontinuation of dialysis, and/or recovery of function at any time in the measurement month.

**Measure Type:** Process

**Data Source:** Electronic Health Data; Electronic Health Records

**Level of Analysis:** Facility



## **Appendix B: KCQA Home Dialysis Retention Measure**

**Description:** Percent of all new home dialysis patients in the measurement year for whom  $\geq 90$  consecutive days of home dialysis was achieved.

**Numerator Statement:** Patients from the denominator who achieved  $\geq 90$  consecutive days of home dialysis in the measurement year.

**Denominator Statement:** The total number of eligible new home dialysis patients attributed to the dialysis facility during the measurement year.

**Denominator Exclusions:** Denominator patients who are discharged from the facility for any of the following events occurring  $< 90$  days after meeting the 30-day eligibility criterion are excluded:

- Transplant;
- Death;
- Discontinuation of dialysis;
- Recovery of function;
- Admission to hospice; and/or
- Admission to nursing home or other LTCF.

**Measure Type Outcome:** Intermediate Clinical Outcome

**Data Source:** Electronic Health Data; Electronic Health Records

**Level of Analysis:** Facility