



February 20, 2023

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: [CMS-10823] Agency Information Collection Activities: Proposed Collection; Comment Request on End Stage Renal Disease (ESRD) Quality Incentive Program (QIP): Study of Quality and Patient Experience

The National Kidney Foundation (NKF) commends the Centers for Medicare and Medicaid Services (CMS) for recognizing the need to significantly improve the quality of care and patient experience within dialysis facilities. NKF, a leader on behalf of the 37 million Americans with chronic kidney disease (CKD), including the almost 800,000 with kidney failure, agrees with CMS ESRD QIP administrators that improving patient care, reducing health disparities, and promoting health equity should continue to be top priorities in alignment with both the *CMS Framework for Health Equity* and the *Advancing American Kidney Health* initiative.

We value the opportunity to provide stakeholder feedback on the established research questions related to dialysis quality, access to care, health equity, and quality of life for individuals with ESRD; however, we believe these primary questions should expand the focus not only to include in-center dialysis experience but also capture home dialysis and the barriers to increased utilization. Home hemodialysis and peritoneal dialysis are the two home dialysis modalities currently offered in the US. In the last decade the percentage of incident dialysis patients performing home dialysis increased from 6.8% to 13.3%.¹ NKF will be providing comments on both the established research questions and areas for possible inquiries into vital aspects of home dialysis for your review and consideration.

I. Comments on established research questions related to dialysis quality, access to care, health equity, and quality of life:

1. What aspects of patient dialysis care do patients report as a priority?

¹ 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, 2022. <https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

Patients have reported to NKF that both equitable access to care and the timeliness of their care upon arrival at a dialysis facility are most important concerns.

Due to increasing demand for dialysis services as a result of both increasing numbers of individuals diagnosed with ESRD annually² and staff shortages exacerbated by the COVID-19 pandemic³, patients are experiencing higher than normal wait times to begin their treatments upon arrival at dialysis centers and decreased acceptance rates to dialysis facilities of their choice. This results in greater than the average 3-4 hours of treatment time per patient being spent within facilities, negatively affecting patient priorities and preferences for their well-being and lifestyle. Further, a significant number of dialysis units have closed over the last year. During the third quarter of 2022, DaVita closed 44 dialysis centers in the United States.⁴ This has forced many dialysis patients to travel further in order to obtain this life-saving treatment as well as longer hospital stays as patients cannot be discharged from the inpatient dialysis units due to lack of an outpatient dialysis unit. Additionally, intense post-treatment fatigue has also been reported by patients to negatively impact their functional status and life-goal directed care, a core patient-centric outcome of care.

2. How, if at all, do dialysis facilities evaluate the quality of care they provide?

Quality of care is evaluated through several patient surveys, such as the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) and the Press Ganey Patient Satisfaction Survey, as well as other ESRD QIP quality performance and reporting metrics.

While the ICH CAHPS is the only patient-reported measure currently within the ESRD QIP focused on addressing patient experience through multiple domains such as Nephrologists' Communication and Caring, Quality of Dialysis Center Care and Operations and Provision of Information to Patients, some providers feel that ICH CAHPS data is not helpful to their quality improvement efforts. Very few patients complete the survey, particularly individuals with fewer socioeconomic advantages and greater illness burden. Patients have reported that the survey continues to fall

² 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, 2022. <https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

³ Stern L, Waikar S. Time to Expand Access and Utilization of Home Dialysis: Lessons From the COVID-19 Pandemic. Mayo Clinic Proc. 2020; 95(7):1323-1324. <https://doi.org/10.1016/j.mayocp.2020.04.038>

⁴ DaVita Inc. DaVita Inc. 3rd Quarter 2022 Results. [Internet]. Denver (CO): PRNewswire; 2022 Oct 28 [cited 2023 Feb 20]. <https://investors.davita.com/2022-10-28-DaVita-Inc-3rd-Quarter-2022-Results#:~:text=During%20the%20third%20quarter%20of,centers%20in%20the%20United%20States>

short in accurately capturing the outcome of their true and overall in-center experience. This limits the tool's effectiveness as many facilities do not obtain aggregate results at a level that can be used to achieve progressive change. Another concern regarding the ICH-CAHPS is that it does not include home dialysis patients and there are currently no validated tools for the assessment of patient experience across dialysis modalities.

Further, many of the measures in the ESRD QIP concentrate on the evaluation of biochemical markers, administrative care coordination outcomes, clinical care, and one on infection safety – areas where facilities do well -- but overlook or oversimplify domains that are important to patients. For example, the Standardized Fistula Rate promotes a “one size fits all” approach to vascular access that does not allow for clinical considerations or patient preferences that preclude evaluation or maturation of a fistula. Similarly, the standardized transfusion ratio measure may be leading to the undertreatment of anemia, a condition that is increasing among dialysis patients and that has an enormous effect on a patient's quality of life.

3. What strategies do providers and dialysis facilities use to improve access to care for underserved populations?

Providers and dialysis facilities have deployed a multipronged approach to improve access to care for underserved populations by addressing specific social risk factors, including transportation to centrally located facilities, socioeconomic status and attainable treatment coverage, and barriers to remote healthcare. Most importantly, NKF continues to advocate for appropriate data collection and application.

To address the need for access to centrally located dialysis facilities, providers have made locations accessible along the routes of public transportation lines. Many facilities also participate in the 340B Drug Pricing Program to acquire the most competitive treatment prices for patients possible. Partnerships with local non-profit foundations enable facilities to access patient support resources managed by in-house social workers, such as limited financial assistance for individual patients, educational programs, and other logistical support. Telehealth is a tool frequently utilized to assist patients overcome barriers to access remote healthcare services.

Data collection on patient social risk factors has been identified as a key element in providing patient-centered dialysis care. Constraints throughout the dialysis service line to collect and deploy these data include patient privacy, overburdened staff, patient survey fatigue, and provider reporting burden. Another important consideration is the standardization of data collection and reporting to authoritative

agencies, particularly through the End Stage Renal Disease Quality Reporting System (EQRS). To achieve health equity, data points to alleviate disparities in kidney disease should include census tract and patient addresses, employment, education, access to nutrition, and exposure to toxic environments. Collected data could be reported on Dialysis Facility Compare (DFC) and should be used for targeted facility incentives and patient interventions, ultimately decreasing the cost of care.

4. What do patients, providers, and stakeholder organizations believe contributes to high quality of life for patients with ESRD? Do perceptions vary by respondent type or respondent characteristics?

Patients, providers, and stakeholder organizations believe patient choice regarding Kidney Replacement Therapy (KRT) and shared decision making throughout their continuum of care contributes to the highest quality of life for patients with ESRD.

Of significant concern to patients is their autonomy of choice regarding dialysis modality. Often, there is potential for patients to feel pressured into a treatment modality that is not aligned with their preferences and goals. Ideally, empowered patients would have all the education and provider-support necessary to decide whether in-center hemodialysis, home hemodialysis, home peritoneal dialysis (PD), kidney transplantation, or conservative management is the best fit for their life goals.

The ESRD Vascular Access Life Plan is a vital tool for shared decision making by the patient and their coordinated-care team because it is an iterative process that evaluates access strategies in alignment with the “patient’s medical, social, and other life circumstances and goals” towards the selection of the best modality choice.⁵ Healthcare outcomes valued most by patients on hemodialysis in relation to high-quality of life include “vascular access problems, dialysis adequacy, fatigue, cardiovascular disease and mortality”.⁶ Healthcare outcomes valued most by patients on peritoneal dialysis in relation to high-quality of life include “PD infection, cardiovascular disease, mortality, PD failure and life participation,”⁷ in addition to

⁵ 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. <https://doi.org/10.1053/j.ajkd.2019.12.001>

⁶ Evangelidis N, Tong A, Manns B, et al. Developing a Set of Core Outcomes for Trials in Hemodialysis: An International Delphi Survey. *Am J Kidney Dis.* 2017; 70(4):464-475. <https://doi:10.1053/j.ajkd.2016.11.029>

⁷ Manera K, Johnson D, Craig J, et al. Establishing a Core Outcome Set for Peritoneal Dialysis: Report of the SONG-PD (Standardized Outcomes in Nephrology-Peritoneal Dialysis) Consensus Workshop. *Am J Kidney Dis.* 2020; 75(3):404-412. <https://doi:10.1053/j.ajkd.2019.09.017>

“residual kidney function, volume status and dialytic solute removal and to minimize treatment burden”.⁸

Perceptions of patient choice do indeed vary by respondent type or characteristics. Many patients are not initially familiar with a multidisciplinary care model. It takes time for patients and their care partners to acclimate to this new operational reality and feel safe and confident enough to champion their choice preferences, especially depending on their social risk factors previously mentioned. One specific example in which perceptions of quality of life would differ by respondent type is of patients experiencing differential dialysis care as a result of neighborhood segregation. Patients from structurally disadvantaged groups often experience dialysis care in facilities that are less likely to offer successful paths to modality choice or transplantation.

5. How do dialysis facilities measure patient satisfaction and quality of life?

NKF would like to emphasize that patient satisfaction and quality of life are mutually exclusive and the measurement of each are ideally unique. Patient satisfaction is routinely evaluated through comprehensive grievance reports and the ICH-CAHPS survey. Patient quality of life is evaluated through validated measurement tools, such as the Kidney Disease Quality of Life -36 (KDQOL-36) and the chronic kidney disease (CKD)-specific QOL impact scale (CKD-QOL).

Patient experience and satisfaction in the care setting is routinely vetted through questionnaires by facility staff administered on paper, by phone, or in person. One way patient quality of life, specifically aspects of functional status and social and psychological well-being, are most often captured is through the Kidney Disease Quality of Life -36 (KDQOL-36) instrument. In compliance with the ESRD Facility Conditions for Coverage, this instrument is integrated within patient care plans and allows for promptly tailored clinical interventions that meet the expectations of patients and their care partners. The CKD-specific QOL impact scale improves upon the KDQOL-36 instrument in that the CKD-QOL “better captures the QOL effects of differences in CKD treatment status and severity on patient-reported outcomes.”⁹

6. How do dialysis providers and stakeholder organizations think quality of life for dialysis patients has changed over time? What was the impetus for that change?

⁸ Brown E, Blake P, Boudville N, et al. International Society for Peritoneal Dialysis practice recommendations: Prescribing high-quality goal-directed peritoneal dialysis. *Perit Dial Int.* 2020; 40(3):244-253. <https://doi.org/10.1177/0896860819895364>

⁹ Ware J, Richardson M, Meyer K, Gandek B. Improving CKD-Specific Patient-Reported Measures of Health-Related Quality of Life. *J Am Soc Nephrol.* 2019; 30(4):664-677. <https://doi:10.1681/ASN.2018080814>

Optimal quality of life for dialysis patients continues to materialize through provider, patient, and stakeholder collaboration on the balance between individualized care and population level priorities.

While there is much more progress to be made, many technological advancements have accrued since the start of the Medicare ESRD program and providers and patients have observed marked improvement in quality of life. One noted example is the advancement in the treatment of anemia with Erythropoiesis-Stimulating Agents (ESAs), as patients are no longer requiring frequent blood transfusions and developing heart and liver failure from iatrogenic iron overload.

Quality measures on the effectiveness of dialysis care have historically been standardized and focused on the population level. Priorities were on clear clinical outcomes assessed by metrics including dialysis adequacy (Kt/V), vascular access type, and bloodstream infections. In a movement to place the needs and values of patients at the center of “measuring health care quality, safety, value, outcomes, and patient experiences” through “data collection, data reporting, and decisions about how measures are used,” a 2017 report by the American Institutes for Research determined that five principles were of the utmost priority of future measure development: patient-driven, holistic, comprehensible/timely, transparent, and co-created.¹⁰ Dialysis-specific healthcare measures should continue to build upon these principles. Care administered to patients today include a focus on their symptoms as core outcomes, daily well-being, and their life goals.

II. Comments on the significance of patient access to home dialysis modalities and the patient and caretaker experience:

NKF supports efforts to better serve ESRD patients who are ineligible to participate in home dialysis or elect in-center dialysis as their preferred care choice. In support of national efforts to increase the uptake and retention of home dialysis patients, NKF offers information regarding the common barriers to home dialysis, educational opportunities for home dialysis utilization, and a roadmap for the evaluation of patient-centered home dialysis treatment.

¹⁰ American Institutes for Research. Principles for Making Health Care Measurement Patient-Centered. 2017; <https://www.air.org/sites/default/files/Patient-Centered-Measurement-Principles-April-2017.pdf>

1. Common barriers to home dialysis:

Home Dialysis Modality	Barrier for Implementation
Peritoneal Dialysis (PD)	Lack of storage space for PD supplies in patient homes
	Inability of patients to lift heavy boxes/bags
	PD catheter infections
	Homelessness and housing instability ¹¹
	Requirement for in-home adult caregiver
Home Hemodialysis (HHD)	Patient fear of cannulation
	Burden on patient/family/caregivers
	Portability
	Homelessness and housing instability ¹²
	Requirement for in-home adult caregiver

2. Home dialysis awareness, mentorship and education for providers, patients, and care partners:

Persistent gaps in provider knowledge on home dialysis significantly impact patient awareness and education on home dialysis. To address these gaps, providers can participate in multimodal educational programs and engage in mentorship programs with experts from high-performing home dialysis facilities to increase their knowledge on the home dialysis infrastructure, unique patient populations, dialysis access creation and maintenance, home dialysis training and prescription, infectious complications, telemedicine, and transitions between home hemodialysis and peritoneal dialysis.¹³

The commitment of care partners is also vital to the long-term success of patients on home dialysis and decreased abandonment rates. Patients and care partners can preemptively screen for feelings of stress, burnout, isolation and value and recruit the assistance of healthcare personnel for tailored interventions when warranted.¹⁴

¹¹⁻¹² Novak TK, Baweja M. Housing: A Critical Contributor to Kidney Disease Disparities. *J Am Soc Nephrol.* 2022;33(8):1471-1473. <https://doi:10.1681/ASN.2022040424>

¹³⁻¹⁴ Chan C, Collins K, Ditschman E, et al. Overcoming Barriers for Uptake and Continued Use of Home Dialysis: An NKF-KDOQI Conference Report. *Am J Kidney Dis.* 2020; 75(6):926-934. <https://doi.org/10.1053/j.ajkd.2019.11.007>

3. Home dialysis quality roadmap:

Quality domains relevant to home dialysis include home dialysis access, clinical care, safety, retention, and Quality of Life (QoL). A home dialysis access measure for practical purposes, can be modified for use in the QIP from the ETC model. The home dialysis access domain should also include patient-reported assessments of whether the individual was given a choice of modality, meaningful education on those choices and whether they are being treated with the modality they prefer. Measures in the clinical care domain should account for residual kidney function (RKF) incorporation into dialysis prescription and dosing, intensive hemodialysis, volume status and blood pressure control. Evaluation of retention would focus on the proficiency of training and burnout of the patients and their care partners. We acknowledge that quality of life is unique to each individual, is affected by processes outside of dialysis, and does not necessarily correlate with quality of care. Thus, in the development of QoL tools, elements of the ESRD Vascular Access Life Plan for shared decision making mentioned previously should be employed. The ESRD Vascular Access Life Plan includes an initial modality plan or choice and access plan, each of which is associated with goals and contingency plans. The person living with ESRD participates in the plan with the interdisciplinary dialysis care team that is documented and updated at least annually.

The National Kidney Foundation (NKF) applauds CMS for its acute attention to persistent knowledge gaps across the dialysis landscape and commitment to information gathering and stakeholder recommendations. NKF is proud to offer support and partnership as a patient advocacy organization throughout the duration of this endeavor. Please contact Ivory Harding, Quality and Regulatory Affairs Directors, at ivory.harding@kidney.org with any questions.

Sincerely,



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