Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to sub criterion 1b).

Brief Measure Information

NQF #: 3722

Corresponding Measures:

Measure Title: Home Dialysis Rate

Measure Steward: Kidney Care Quality Alliance

sp.02. Brief Description of Measure: Percent of all dialysis patient-months in the measurement year in which the patient was dialyzing via a home dialysis modality.

1b.01. Developer Rationale:

As previously noted, dialysis modality selection impacts both clinical and patient-reported outcomes.[1] While PD yields similar short- and long-term survival to in-center HD for individuals with ESKD,[2] 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.[3],[4] 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.[5] Moreover, with more frequent therapies, both PD and HHD eliminate the prolonged two-day interdialytic gap that can adversely affect outcomes.[6] Nevertheless, home modalities are still used at substantially lower rates in the U.S. than in other developed nations,[7] hovering at only around 15%.[8]

Accordingly, increasing home dialysis is a major objective of the ESRD Treatment Choices (ETC) Payment Model launched CMS in January 2021,[9] and home dialysis utilization has been identified as one of the performance metrics that will be used in the program.[10] The KCQA Home Dialysis Measure Set (Home Dialysis Rate [NQF 3722] and Home Dialysis Retention [NQF 3725]) was conceptualized and developed to fill that role.

The Home Dialysis Rate Measure 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)[11] 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[12] 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 following logic model illustrates the relationship between the individual measure components, process interventions, and the desired health outcomes, which include lowering patient mortality, hospitalization, and cardiovascular risk, improving patients' quality of life, and reducing cost of care:

Diagram 1: Logic model diagram illustrating how the dialysis facility/HRR is being measured and how the measure components are connected to patient health outcomes.

HOME DIALYSIS RATE LOGIC MODEL

Again, while the Home Dialysis Rate Measure can stand alone, we recommend it be paired with the accompanying KCQA Home Dialysis Retention Measure (NQF 3725) for optimal results. The paired set is intended to promote steady, deliberate performance improvement over time by addressing *both* sides of the home dialysis utilization equation—uptake and retention. The "guardrail" Home Dialysis Retention Measure is intended to counterbalance the unopposed incentivization of home prescription that might occur if a rate measure were implemented alone, minimizing the potential adverse consequences of unchecked home dialysis growth. 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.

[1] 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.

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

[3] 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.

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

[6] 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.

[7] 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.

[8] 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.)

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

[10]*Supra,* note 35.

[11] 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.

[12] Patients not meeting any of the exclusion criteria in the measurement month.

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sp.12. Numerator Statement:

Patient-months[1] 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.

References:

1. A patent-month construct is used to account for patients' potentially varying time contributions to both the numerator and denominator.

sp.14. Denominator Statement:

All dialysis patient-months[1] (in-center and/or home) attributed to the dialysis facility (or aggregate HRR unit)[2] during the measurement year.

References:

1. A patent-month construct is used to account for patients' potentially varying time contributions to both the numerator and denominator.
2. 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 wholly or in part by the company.

sp.16. 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

sp.28. Data Source:

Electronic Health Data

Electronic Health Records

sp.07. Level of Analysis:

Facility

Other

IF Endorsement Maintenance – Original Endorsement Date:

Most Recent Endorsement Date:

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title: KCQA Home Dialysis Utilization Measures

#3722 - Home Dialysis Rate

#3725 - Home Dialysis Retention

sp.03. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?:

The KCQA Home Dialysis Rate Measure can stand alone; however, we recommend it be paired with the accompanying KCQA Home Dialysis Retention Measure for optimal results.

Increasing home dialysis is a major objective of the Advancing American Kidney Health Initiative and the ensuing ESRD Treatment Choices (ETC) Payment Model, launched by the Centers for Medicare & Medicaid Services (CMS) in January 2021. The ETC model, which initially proposed an 80% incident home dialysis or transplantation rate by the end of 2025, provides significant financial incentives—and penalties—to improve home dialysis utilization. While the initiative has the potential to dramatically change nephrology and dialysis care in the United States, there is concern among stakeholders that this unilateral focus on home dialysis growth in a healthcare system not adequately prepared for such an influx may lead to suboptimal outcomes and have unintended, prolonged negative effects on home dialysis. Incentivizing a rapid rise in the use of home dialysis in the absence of safeguards and a sufficiently robust infrastructure to support such growth will certainly lead to increased technique failure rates. It may also subject many patients to a treatment modality for which they have not received adequate education or training, and may even inadvertently result in infringement on patient choice.

To address such concerns, KCQA's "Home Dialysis Measure Set" has been developed and designed 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 rate measure were implemented alone, minimizing the potential adverse consequences of unchecked home dialysis growth. 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.

1. Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria

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Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

Current Submission:

Updated evidence information here.

Previous (Year) Submission:

Evidence from the previous submission here.

1a.01. Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

[Response Begins]

Dialysis modality selection impacts both clinical and patient-reported outcomes.[1] There is now copious empirical evidence demonstrating that peritoneal dialysis (PD) yields similar short- and long-term survival for people with kidney failure to in-center hemodialysis (HD).[2] Importantly, PD also enhances patient autonomy and quality of life, is associated with preservation of residual kidney function, and is less expensive to deliver.[3],[4] 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.[5] Moreover, with more frequent therapies, both PD and HHD eliminate the prolonged two-day interdialytic gap that can adversely affect outcomes.[6] However, despite these known advantages and strong support among healthcare providers and patients as preferable to in-center hemodialysis, home dialysis has been used at substantially lower rates in the U.S. than in other developed nations,[7] hovering at only around 15 percent.[8]

Accordingly, increasing home dialysis is a major objective of the Advancing American Kidney Health Initiative and the ensuing ESRD Treatment Choices (ETC) Payment Model, launched by the Centers for Medicare & Medicaid Services (CMS) in January 2021.[9] The model is intended to encourage greater use of home dialysis and kidney transplants for Medicare beneficiaries with ESRD, while reducing Medicare expenditures and preserving or enhancing the quality of care furnished to beneficiaries with ESRD. As such, uptake of home dialysis modalities has been identified by CMS as one of the metrics upon which facilities will be evaluated within the ETC program. The KCQA Home Dialysis Measure Set (Home Dialysis Rate [NQF 3722] and Home Dialysis Retention [NQF 3725]) was conceptualized and developed to fill that role.

The Home Dialysis Rate Measure 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)[10] within the given measurement year. The basic premise of the measure is to incentivize prescription of and preparation for home modalities for all clinically appropriate patients, in accordance with patient preference. The logic model below illustrates the relationship between the individual measure components, process interventions, and the desired health outcomes, which include lowering patient mortality, hospitalization, and cardiovascular risk, improving patients' quality of life, and reducing cost of care:

Diagram 1: Logic model diagram illustrating how the dialysis facility/HRR is being measured and how the measure components are connected to patient health outcomes.

HOME DIALYSIS RATE LOGIC MODEL

Specifically, adoption of the Home Dialysis Rate Measure will incentivize the facility/HRR to first identify appropriate home dialysis candidates among eligible[11] in-center hemodialysis patients, and to then implement process interventions (e.g., effective education, appropriate patient preparation/training/support) to increase both home dialysis uptake and retention among those candidates.

We note that while the KCQA Home Dialysis Rate Measure can stand alone, we recommend it be paired with the accompanying KCQA Home Dialysis Retention Measure (NQF 3725) for optimal results. At current, approximately one-quarter of all patients who initiate home dialysis will return to in-center hemodialysis within two years.[12] While the ETC initiative has the potential to dramatically change nephrology and dialysis care in the United States, there is concern among stakeholders that this unilateral focus on home dialysis growth in a healthcare system not adequately prepared for such an influx may lead to suboptimal outcomes and have unintended, prolonged negative effects on home dialysis. Incentivizing a rapid rise in the use of home dialysis in the absence of safeguards and a sufficiently robust infrastructure to support such growth will certainly lead to increased technique failure rates. It may also subject many patients to a treatment modality for which they have not received adequate education or training, and may even inadvertently result in infringement on patient choice.

To address such concerns, KCQA's "Home Dialysis Measure Set" has been developed and designed 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 rate measure were implemented alone, minimizing the potential adverse consequences of unchecked home dialysis growth. 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.

[1] 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.

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

[3] 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.

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

[6] 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.

[7] 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.

[8] 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.)

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

[10] 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.

[11] Patients not meeting any of the exclusion criteria in the measurement month.

[12] 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.)

[Response Ends]

1a.02. Select the type of source for the systematic review of the body of evidence that supports the performance measure.

A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data.

[Response Begins]

Other (specify)

[Other (specify) Please Explain]

To date, there are no relevant clinical practice guidelines, USPSTF recommendations, systematic reviews, or formal randomized controlled studies addressing home dialysis utilization. As such, evidence for the KCQA Home Dialysis Measures is based on a large body of observational studies in the U.S. as well as Canada, several European countries, Australia, New Zealand, and Japan.

[Response Ends]

If the evidence is not based on a systematic review, skip to the end of the section and do not complete the repeatable question group below. If you wish to include more than one systematic review, add additional tables by clicking "Add" after the final question in the group.

Evidence - Systematic Reviews Table (Repeatable)

Group 1 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

[Response Begins]

N/A; no pertinent systematic review of evidence available.

[Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

[Response Begins]

N/A; no pertinent systematic review of evidence available.

[Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

[Response Begins]

N/A; no pertinent systematic review of evidence available.

[Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

[Response Begins]

N/A; no pertinent systematic review of evidence available.

[Response Ends]

1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

[Response Begins]

N/A; no pertinent systematic review of evidence available.

[Response Ends]

1a.08. Provide all other grades and definitions from the recommendation grading system.

[Response Begins]

N/A; no pertinent systematic review of evidence available.

[Response Ends]

1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

[Response Begins]

N/A; no pertinent systematic review of evidence available.

[Response Ends]

1a.10. Provide the estimates of benefit, and consistency across studies.

[Response Begins]

N/A; no pertinent systematic review of evidence available.

[Response Ends]

1a.11. Indicate what, if any, harms were identified in the study.

[Response Begins]

N/A; no pertinent systematic review of evidence available.

[Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

[Response Begins]

N/A; no pertinent systematic review of evidence available.

[Response Ends]

1a.13. If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, describe the evidence on which you are basing the performance measure.

[Response Begins]

Again, to date there are no relevant clinical practice guidelines, USPSTF recommendations, systematic reviews, or formal randomized controlled studies addressing home dialysis modalities uptake. As such, evidence for the Home Dialysis Rate Measure is based on a large body of observational studies in the U.S. as well as Canada, several European countries, Australia, New Zealand, and Japan. (See evidence synthesis in Question 1a.14.)

Additionally, KCQA convened a Technical Home Dialysis Expert Workgroup in summer 2021 to conceptualize and develop the Home Dialysis Measures. The Workgroup was made up of one ESRD patient that had experience with both in-center and home dialysis, five clinicians that treat in-center and home ESRD dialysis patients (adult and pediatric nephrologists and nephrology nurses), one dialysis facility administrator/manager, and one epidemiologist with over 15 years of research focusing primarily on home dialysis. (The *Workgroup Roster* is also included in the "Additional Materials" section of this submission.) Over the course of the multi-month measure development process, there was strong consensus among Workgroup members that home dialysis remains underutilized in the U.S. and that an actionable quality measure that will promote steady, sustainable performance improvement over time is needed and would be useful to patients, providers, and other stakeholders. The Workgroup unanimously approved the measure specifications coming out of that process, now submitted to NQF for endorsement consideration. (*Meeting Summaries* can be accessed here.) The measures were also unanimously supported by KCQA's broad-based 15-member Steering Committee and full Membership, comprised of patients/advocates, physicians, nurses, researchers, and manufacturers from organizations across the full range of KCP's membership. (Also see both rosters in the "Additional Materials" section.)

[Response Ends]

1a.14. Briefly synthesize the evidence that supports the measure.

[Response Begins]

Home dialysis is underutilized. Home dialysis rates remain low in the United States compared with many other countries, hovering around 15%.[1],[2] Barriers to home dialysis utilization and growth are multifactorial:[3]

- Patient factors include a lack of patient awareness and/or education, concerns of perceived burden and out of pocket costs, fear of dialyzing at home, insufficient housing or storage space for dialysis supplies, and geographic inaccessibility, among others.
- Clinical barriers include inadequate or absent clinician and staff training and experience and healthcare team biases.
- Operational issues include the lack of a sufficiently robust infrastructure to support home modalities, small facility size, and inadequate staffing and other resources.

Studies have also identified black race, Hispanic ethnicity, and older age as predictors of low uptake of home dialysis.[4],[5]

Home dialysis is associated with equivalent clinical outcomes and superior patient-reported outcomes. Because of the lack of RCTs comparing dialysis modalities and outcomes, current evidence is largely observational in nature. More than two decades of publications show similar survival between patients undergoing PD and those receiving conventional, thrice-weekly in-center HD, with some studies showing an advantage with PD as an initial modality and mixed evidence around longer term outcomes. As such, in-center and home dialysis are generally considered equivalent with respect to hospitalization rates and mortality.[6],[7] Nevertheless, individuals receiving home dialysis consistently score higher in physical and mental quality of life

domains in patient-reported measures compared to their in-center counterparts.[8],[9] It has thus been argued that in clinical practice, modality choice should be individualized with the aim of maximizing quality of life, patient experience, and achieving patient-centered goals.[10]

Analyses of patient preferences support increased home dialysis use. Given the equivalent clinical outcomes and improved health-related quality of life associated with home dialysis within the context of persistent underutilization, it is not surprising that a mismatch between patients' stated modality preference and the modality used at dialysis start has been identified, the most common scenario being initiation on in-center HD despite a preference for a home therapy.[11],[12],[13] Studies examining patients' perspectives on modality choice also indicate that approximately 30 percent of chronic dialysis patients report they do not believe they made a fully informed choice regarding modality, with this finding being most prevalent among in-center HD patients.[14],[15],[16],[17] Decision-making efficacy and satisfaction of modality selection has also been reported as greater among PD vs in-center HD patients.[18] The reasons for these findings are multifactorial, with the above-noted clinical, operational, and patient home dialysis barriers identified as contributors.[19],[20]

Increasing home dialysis utilization is now a major CMS objective. In light of the above, CMS launched the ESRD Treatment Choices (ETC) Payment Model in January 2021 to encourage greater use of home dialysis for Medicare beneficiaries to reduce costs while preserving or enhancing the quality of ESRD care.[21] Home dialysis utilization has been identified by CMS as one of the metrics upon which dialysis facilities and organizations will be evaluated within the ETC program, and presumably also with the ESRD Quality Incentive Program (QIP) soon thereafter.[22] The KCQA Home Dialysis Rate Measure (NQF 3722) was conceptualized and developed to fill that role.

[1] 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.

[2] Briggs V, Davies S, Wilkie M. International variations in peritoneal dialysis utilization and implications for practice. *Am J Kidney Dis.* 2019 Jul;74(1):101-110.

[3] Ibid.

[4] 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.

[5] Shen JI, Chen L, Vangala S, et al. Socioeconomic factors and racial and ethnic differences in the initiation of home dialysis. Kidney Med. 2020;2(2):105-115.

[6] Schulman G. Mortality and treatment modality of end-stage renal disease. *Ann Intern Med.* 2005;143:229–231.

[7] Suri RS, Li L, Nesrallah GE. The risk of hospitalization and modality failure with home dialysis. *Kidney Int.* 2015;88:360–368.

[8] Budhram B et al. A Comparison of patient-reported outcome measures of quality of life by dialysis modality in the treatment of kidney failure: A systematic review. *Can J Kidney Health Dis.* 2020 Oct 19;7:2054358120957431.

[9] Brown EA, Zhao J, McCullough K, Fuller DS, et al. Burden of kidney disease, health-related quality of life, and employment among patients receiving peritoneal dialysis and in-center hemodialysis: Findings from the DOPPS Program. *Am J Kidney Disease.* 2021;78(4):489-500e1.

[10] Lee MB, Bargman JM. Survival by dialysis modality—Who cares? *Clin J Am Soc Nephrol.* 2016;11(6):1083-1087,

[11] Pyart R et al. Peritoneal dialysis: Turning choice into reality. *Perit Dial Int.* 2018 Sep-Oct;38(5):328-333.

[12] Keating PT et al. The impact of patient preference on dialysis modality and hemodialysis vascular access. *BMC Nephrol.* 2014 Feb 22;15:38.

[13] Liebman SE et al. Differences between dialysis modality selection and initiation. *Am J Kidney Dis.* 2012 Apr;59(4):550-557.

[14] Dahlerus C et al. Patient perspectives on the choice of dialysis modality: Results from the Empowering Patients on Choices for Renal Replacement Therapy (EPOCH-RRT) Study. *Am J Kidney Dis.* 2016 Dec;68(6):901-910.

[15] Van Biesen W et al. Patients' perceptions of information and education for renal replacement therapy: An independent survey by the European Kidney Patients' Federation on information and support on renal replacement therapy. *PLoS One.* 2014 Jul 31;9(7):e103914.

[16] Song MK et al. Patient perspectives on informed decision-making surrounding dialysis initiation. *Nephrol Dial Transplant.* 2013 Nov;28(11):2815-2823.

[17] Winterbottom AE et al. Patient stories about their dialysis experience biases others' choices regardless of doctor's advice: An experimental study. *Nephrol Dial Transplant.* 2012 Jan;27(1):325-331.

[18] Zee J et al. Perceptions about the dialysis modality decision process among peritoneal dialysis and in-center hemodialysis patients. *BMC Nephrol.* 2018 Oct 29;19(1):298.

[19] Chan CT et al. Dialysis initiation, modality choice, access, and prescription: Conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. *Kidney Int.* 2019 Jul;96(1):37-47.

[20] Ibid.

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

[22]CMS. "Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities." 86 *Fed. Reg.* 68594, 68599 (Dec. 3, 2021) ("Among other things, the Specialty Care Models final rule finalized the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model, which is designed to encourage greater use of home dialysis and kidney transplants for Medicare beneficiaries with ESRD, while reducing Medicare expenditures and preserving or enhancing the quality of care furnished to beneficiaries with ESRD. As described in the Specialty Care Models final rule, both of these modalities have support among health care providers and patients as preferable alternatives to in-center hemodialysis, but utilization has been less than in other developed nations").

[Response Ends]

1a.15. Detail the process used to identify the evidence.

[Response Begins]

A literature search of guidance documents and peer-reviewed articles for the treatment of end stage renal disease (ESRD), also known as end stage kidney disease (ESKD), published from 2011 to date[1] *was conducted* using PubMed, MEDLINE, Science Direct, and Scopus databases. We evaluated studies that examined:

- the epidemiology and characteristics of home dialysis utilization;
- educational interventions and processes to support shared-decision making;
- home dialysis modalities vs in-center hemodialysis outcomes; and
- the association of home modalities with comorbidities and other health outcomes.

After removing duplicates, publications not in English, and articles outside the scope of the objective, our search yielded 43 unique articles.

[1] We limited our search to publications from 2011 onward to reflect the removal of financial disincentives to home dialysis that occurred with CMS's implementation of a bundled payment system that provided equal pay for PD and in-center HD.

[Response Ends]

1a.16. Provide the citation(s) for the evidence.

[Response Begins]

Citations:

1. Boateng EA, East LJ. The impact of dialysis modality on quality of life: A systematic review. *Ren Care.* 2011;37(4):190-200.
2. Briggs V, Davies S, Wilkie M. International variations in peritoneal dialysis utilization and implications for practice. *Am J Kidney Dis.* 2019;74(1):101-110.
3. Brown EA, Zhao J, McCullough K, Fuller DS, et al. Burden of kidney disease, health-related quality of life, and employment among patients receiving peritoneal dialysis and in-center hemodialysis: Findings from the DOPPS Program. *Am J Kidney Disease.* 2021;78(4):489-500e1.
4. Budhram B et al. A Comparison of patient-reported outcome measures of quality of life by dialysis modality in the treatment of kidney failure: A systematic review. *Can J Kidney Health Dis.* 2020;7:2054358120957431.
5. Chan CT et al. Dialysis initiation, modality choice, access, and prescription: Conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. *Kidney Int.* 2019;96(1):37-47.
6. Chanouzas D, Ng KP, Fallouh B, Baharani J. What influences patient choice of treatment modality at the pre-dialysis stage? *Nephrol Dial Transplant.* 2012;27(4):1542-1547.
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[Response Ends]

1b.01. Briefly explain the rationale for this measure.

Explain how the measure will improve the quality of care, and list the benefits or improvements in quality envisioned by use of this measure.

[Response Begins]

As previously noted, dialysis modality selection impacts both clinical and patient-reported outcomes.[1] While PD yields similar short- and long-term survival to in-center HD for individuals with ESKD,[2] 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.[3],[4] 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.[5] Moreover, with more frequent therapies, both PD and HHD eliminate the prolonged two-day interdialytic gap that can adversely affect outcomes.[6] Nevertheless, home modalities are still used at substantially lower rates in the U.S. than in other developed nations,[7] hovering at only around 15%.[8]

Accordingly, increasing home dialysis is a major objective of the ESRD Treatment Choices (ETC) Payment Model launched CMS in January 2021,[9] and home dialysis utilization has been identified as one of the performance metrics that will be used in the program.[10] The KCQA Home Dialysis Measure Set (Home Dialysis Rate [NQF 3722] and Home Dialysis Retention [NQF 3725]) was conceptualized and developed to fill that role.

The Home Dialysis Rate Measure 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)[11] 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[12] 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 following logic model illustrates the relationship between the individual measure components, process interventions, and the desired health outcomes, which include lowering patient mortality, hospitalization, and cardiovascular risk, improving patients' quality of life, and reducing cost of care:

Diagram 1: Logic model diagram illustrating how the dialysis facility/HRR is being measured and how the measure components are connected to patient health outcomes.

HOME DIALYSIS RATE LOGIC MODEL

Again, while the Home Dialysis Rate Measure can stand alone, we recommend it be paired with the accompanying KCQA Home Dialysis Retention Measure (NQF 3725) for optimal results. The paired set is intended to promote steady, deliberate performance improvement over time by addressing *both* sides of the home dialysis utilization equation—uptake and retention. The "guardrail" Home Dialysis Retention Measure is intended to counterbalance the unopposed incentivization of home prescription that might occur if a rate measure were implemented alone, minimizing the potential adverse consequences of unchecked home dialysis growth. 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.

[1] 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.

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

[3] 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.

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

[6] 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.

[7] 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.

[8] 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.)

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

[10] *Supra,* note 35.

[11] 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.

[12] Patients not meeting any of the exclusion criteria in the measurement month.

[Response Ends]

1b.02. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

While this is a new measure and has not yet been implemented, we calculated 2021 performance scores during measure testing[1,2] at both the facility and the aggregate parent Dialysis Organization (DO) Hospital Referral Region (HRR) unit. Testing encompassed 543,115 patients; 4,937,405 patient-months; 5,792 facilities; and 295 HRRs (with 267 HRRs for each of the participating DOs). The overall distributions and deciles of performance scores are summarized in the following tables.

Facility-Level:

# Facilities	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
5,781	14.49	25.10	0.00	0.00	0.16	19.84	100.00	0.00	0.00	0.00	0.00	8.78	16.62	23.83	37.82

The table illustrates the Distribution and Deciles of Facility Performance Scores, Rate as %

Aggregate HRR Unit Level:[3]

*	# HRRs	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Overall	295	16.58	6.57	0.00	12.52	16.00	19.51	48.02	9.70	11.94	13.55	14.79	17.22	18.33	20.35	24.50
DO 1	267	17.26	11.90	0.00	11.58	15.54	19.43	100.00	7.78	10.81	12.71	14.40	16.78	18.35	20.64	26.20
DO 2	267	16.37	9.21	0.00	11.23	14.87	20.01	97.30	7.52	10.41	12.10	13.79	16.89	18.61	21.20	26.32

The table illustrates the Distribution and Deciles of HRR Performance Scores, Rate as 5

*Cell intentionally left blank.

As can be seen, performance is appreciably higher at the aggregate parent company HRR unit level than at the individual facility level, highlighting the need to recognize the existing structure of the dialysis market to account for home-only facilities. Specifically, parent DOs may send home dialysis patients to such dedicated home-only facilities within a given region, such that some facilities will have *no* home dialysis patients and others will have *only* home dialysis patients. The measure thus allows for aggregation of facilities owned by the same company within a given Hospital Referral Region (HRR) - the same approach used by CMS in the ESRD Treatment Choices (ETC) Program. Specifically, a subsidiary facility's Home Dialysis Rate is aggregated to the facility's aggregation group, which includes all dialysis facilities owned in whole or in part by the same legal entity ("Parent Organization") located in the HRR in which the facility is located. (For instance, if a parent organization had 20 facilities across two HRRs (10 in each), these would be reported as two separate "facilities," one for each HRR.)

References:

1. To account for home dialysis–only facilities within a Hospital Referral Region (HRR), particularly if a parent company sends its home dialysis patients to such a provider, the measure allows for aggregation of facilities owned by the same company within a given HRR. Specifically, a subsidiary facility's Home Dialysis Rate is aggregated to the facility's aggregation group, which includes all dialysis facilities owned in whole or in part by the same legal entity ("Parent Organization") located in the HRR in which the facility is located.
2. Data for measure testing were collected at the facility level, then aggregated to the parent DO HRR level (where applicable). Throughout this form, testing results are presented at both the facility-level and the HRR-level; this approach allows for NQF assessment of how "independent" facilities that are not subsidiaries of any parent company might perform. Additionally, HRR data are presented at the DO-level only where important/necessary to illustrate differences across the DOs; otherwise, the "overall" HRR-level data across both DOs are presented to preserve company anonymity (also see #3 below).
3. To preserve anonymity, data are presented as coming from Dialysis Organization (DO) 1 and 2, where applicable. This nomenclature is random and is randomly scrambled throughout the measure submission documents such that DO 1 in one section might become DO 2 in another section, and vice versa.

[Response Ends]

1b.03. If no or limited performance data on the measure as specified is reported above, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement. Include citations.

[Response Begins]

In addition to the above data generated during testing, we again note that despite the established benefits of home modalities over in-center hemodialysis, home dialysis utilization remains remarkably low in the U.S. In 2019 (the most recent USRDS data available at this time), only 12.6% of incident patients dialyzed at home. And while utilization increased to 18.2% by one year after initiation, it dropped again to 13.1% in prevalent patients—also highlighting the need to assess retention rates.[1] While this represents more than a 30% increase during the past decade, home dialysis use remains lower in the United States than in many other developed economies, where we often see a quarter or more of patients receiving a home-based therapy—e.g., New Zealand (44%), Denmark (27%), Colombia (26%), Australia (24%), Canada (26%).[2] Even following the launch of the ETC Model in January 2021, in which reimbursement rates for home dialysis are boosted for the first three years of the program (3% in 2021, 2% in 2022, and 1% in 2023), 2021 home dialysis rates peaked at only about 17% in new patients in the first 90 days of treatment, indicating considerable and continued room for improvement in this aspect of care. Despite little agreement in the United States as to how many patients should dialyze at home, most members of the kidney community acknowledge that home dialysis rates could increase substantially without reducing patient choice.[3]

[1] 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.

[2] Ibid.

[3] Weiner D, Meyer K. Home dialysis in the United States: To increase utilization, address disparities. *Kidney Med.* 2020;2(2):95-97.

[Response Ends]

1b.04. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

Our analyses of 2021 data during measure testing highlighted notable variations in performance across demographic groups. At both the facility and HRR levels, we saw clear trends by race, with substantially higher home dialysis rates among Whites compared to Black patients, and the highest rates in "Other" races. Additionally, home dialysis use is markedly lower in dual-eligible than non-dual-eligible patients:

*	White	Black	Other	Non-Hispanic	Hispanic	Dual Eligible	Not Dual Eligible
Mean Home Dialysis Rate	15.57	12.90	17.23	14.65	14.21	11.95	15.42

The table illustrates Performance Variation Across Demographic Groups

*Cell intentionally left blank.

[Response Ends]

1b.05. If no or limited data on disparities from the measure as specified is reported above, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in above.

[Response Begins]

In addition to our own findings from above, the most recent USRDS data available at this time indicate that in 2019, Black and Hispanic patients remained less likely than non-Hispanic White patients to be treated with home dialysis: 7.8% of Black patients and 7.9% of Hispanic prevalent patients with kidney failure were treated with home dialysis therapies, compared with 10.8% of non-Hispanic White patients.[1] This is despite the disproportionately high risk of kidney failure in racial and ethnic minority populations, with Black and Hispanic individuals having a 3.4-fold and 1.3-fold greater risk, respectively, compared with non-Hispanic White people.[2] These racial and ethnic disparities cannot be completely explained by geographic, demographic, and clinical factors.[3]

[1] 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.

[2] Ibid.

[3] Shen JI, Chen L, Vangala S, et al. Socioeconomic factors and racial and ethnic differences in the initiation of home dialysis. *Kidney Med.* 2020;2:105–115.

[Response Ends]

2. Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.

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sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see What Good Looks Like).

[Response Begins]

Home Dialysis Rate

[Response Ends]

sp.02. Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

[Response Begins]

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

[Response Ends]

sp.03. Provide a rationale for why this measure must be reported with other measures to appropriately interpret results.

[Response Begins]

The KCQA Home Dialysis Rate Measure can stand alone; however, we recommend it be paired with the accompanying KCQA Home Dialysis Retention Measure for optimal results.

Increasing home dialysis is a major objective of the Advancing American Kidney Health Initiative and the ensuing ESRD Treatment Choices (ETC) Payment Model, launched by the Centers for Medicare & Medicaid Services (CMS) in January 2021. The ETC model, which initially proposed an 80% incident home dialysis or transplantation rate by the end of 2025, provides significant financial incentives—and penalties—to improve home dialysis utilization. While the initiative has the potential to dramatically change nephrology and dialysis care in the United States, there is concern among stakeholders that this unilateral focus on home dialysis growth in a healthcare system not adequately prepared for such an influx may lead to suboptimal outcomes and have unintended, prolonged negative effects on home dialysis. Incentivizing a rapid rise in the use of home dialysis in the absence of safeguards and a sufficiently robust infrastructure to support such growth will certainly lead to increased technique failure rates. It may also subject many patients to a treatment modality for which they have not received adequate education or training, and may even inadvertently result in infringement on patient choice.

To address such concerns, KCQA's "Home Dialysis Measure Set" has been developed and designed 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 rate measure were implemented alone, minimizing the potential adverse consequences of unchecked home dialysis growth. 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.

[Response Ends]

sp.04. Check all the clinical condition/topic areas that apply to your measure, below.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Surgery: General*

[Response Begins]

Renal

Renal: End Stage Renal Disease (ESRD)

[Response Ends]

sp.05. Check all the non-condition specific measure domain areas that apply to your measure, below.

[Response Begins]

Access to Care

Care Coordination

Care Coordination: Transitions of Care

Disparities Sensitive

Health and Functional Status: Quality of Life

Safety

[Response Ends]

sp.06. Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Populations at Risk: Populations at Risk*

[Response Begins]

Adults (Age >= 18)

Children (Age < 18)

Elderly (Age >= 65)

Populations at Risk: Dual eligible beneficiaries of Medicare and Medicaid

Populations at Risk: Individuals with multiple chronic conditions

[Response Ends]

sp.07. Select the levels of analysis that apply to your measure.

Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

Other

[Response Ends]

sp.08. Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED.

[Response Begins]

Ambulatory Care

Home Care

Outpatient Services

Post-Acute Care

[Response Ends]

sp.09. Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials.

Do not enter a URL linking to a home page or to general information. If no URL is available, indicate "none available".

[Response Begins]

https://kidneycarepartners.org/wp-content/uploads/2022/07/KCQA-2022-Measures-Detailed-Specifications_FINAL.pdf

[Response Ends]

sp.12. Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, contact staff. Provide descriptors for any codes. Use one file with multiple worksheets, if needed.

[Response Begins]

Available in attached Excel or csv file

[Response Ends]

Attachment: 3722_Home Dialysis Rate Data Dictionary-508.xlsx

sp.13. State the numerator.

Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome).

DO NOT include the rationale for the measure.

[Response Begins]

Patient-months[1] 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.

References:

1. A patent-month construct is used to account for patients' potentially varying time contributions to both the numerator and denominator.

[Response Ends]

sp.14. Provide details needed to calculate the numerator.

All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

The numerator includes all patient-months from the denominator within which the patient's "Dialysis Setting" was recorded as "Home" as of the final treatment of the given measurement month.

For each patient, determination of the dialysis setting each month will be derived from a combination of EQRS facility-reported clinical and administrative data. Data elements required to identify the numerator:

Data Element	Primary Data Source(s)	Values
Reporting Month	EQRS/CROWNWeb	Jan, Feb, Mar, Apr, May, Jun, Jul, Aug, Sep, Oct, Nov, Dec
Reporting Year	EQRS/CROWNWeb	Clinical Year (YYYY)
Dialysis Setting[1]	EQRS/CROWNWeb	1-Home, 2-Dialysis Facility/Center, 3-SNF/LTCF
Hospital Referral Region (HRR)[2]	CMS data sources	Numerical Value
Facility CCN#	EQRS/CROWNWeb	CROWNWeb Facility Unique Identifier

The table lists the data elements required to calculate the measure numerator.

References:

1. Patients with a missing "Dialysis Setting" are counted in the denominator, but not the numerator. (I.e., missing dialysis setting is counted as in-center.)
2. In recognition of the structure of the dialysis market, if a company (dialysis organization) owns multiple facilities within a given Hospital Referral Region (HRR), it would report an aggregated score for all facilities located within the HRR owned wholly or in part by the company. If, for instance, a parent organization had 20 facilities across two HRRs (10 in each), these would be reported as two separate "facilities," one for each HRR.

[Response Ends]

sp.15. State the denominator.

Brief, narrative description of the target population being measured.

[Response Begins]

All dialysis patient-months[1] (in-center and/or home) attributed to the dialysis facility (or aggregate HRR unit)[2] during the measurement year.

References:

1. A patent-month construct is used to account for patients' potentially varying time contributions to both the numerator and denominator.
2. 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 wholly or in part by the company.

[Response Ends]

sp.16. Provide details needed to calculate the denominator.

All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

The annual denominator patient count includes all dialysis patient-months (both in-center and/or home) attributed[1] to the dialysis facility (or aggregate HRR unit) during the measurement year.

Data elements required to identify the denominator for each patient include:

Data Element	Primary Data Source(s)	Values
Reporting Month	EQRS/CROWNWeb	Jan, Feb, Mar, Apr, May, Jun, Jul, Aug, Sep, Oct, Nov, Dec
Reporting Year	EQRS/CROWNWeb	Clinical Year (YYYY)
Facility Admit Date	EQRS/CROWNWeb	Date
Facility Discharge Date	EQRS/CROWNWeb	Date
Hospital Referral Region (HRR)[2]	CMS data sources	Numerical Value
Facility CCN#	EQRS/CROWNWeb	CROWNWeb Facility Unique Identifier

The table lists the data elements required to calculate the measure denominator.

Note: Patients with a missing "Dialysis Setting" are counted in the denominator, but not the numerator. (I.e., missing dialysis setting is counted as in-center.)

References:

1. Facility attribution is determined as follows:
    - A patient is attributed to a facility 30 days following admission to that facility.
    - If a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 30 days and is then attributed to the destination facility.
    - When a patient is not treated in a single facility for a span of 30 days (e.g., there are two transfers within 30 days of each other), the patient is not attributed to any facility until 30 days of treatment is achieved an any one facility.
2. In recognition of the structure of the dialysis market, if a company owns multiple facilities in a given Hospital Referral Region (HRR), it would report an aggregated score for all facilities located within the HRR owned wholly or in part by the company.

[Response Ends]

sp.17. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

[Response Begins]

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.

[Response Ends]

sp.18. Provide details needed to calculate the denominator exclusions.

All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

Patient-months captured in the denominator count will be excluded if any of the following criteria are met:

- Patient was admitted to the facility for <30 days as of the final day of the measurement month.
- Patient was receiving dialysis for AKI only at any time in the measurement month.
- Patient was enrolled in hospice at any time in the measurement month.
- Patient was residing in a nursing home or other LTCF at any time in the measurement month.
- 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.

The following data elements are required to identify the exclusions:

Data Element	Primary Data Source	Values
Reporting Month	EQRS/CROWNWeb	Jan, Feb, Mar, Apr, May, Jun, Jul, Aug, Sep, Oct, Nov, Dec
Reporting Year	EQRS/CROWNWeb	Clinical Year (YYYY)
Dialysis Setting	EQRS/CROWNWeb	1-Home, 2-Dialysis Facility/Center, 3-SNF/Long Term Care Facility
Facility Admit Date	EQRS/CROWNWeb	Date
Facility Discharge Date	EQRS/CROWNWeb	Date
Discharge Reason	EQRS/CROWNWeb	1 - Death, 2 - Discontinue, 3 - Lost to Follow Up, 4 - Recover Function, 7 - Transplant in US, 8 - Transplant outside US
Discharge Disposition	EQRS/CROWNWeb	2-Hospice, 4-Long Term Care Facility, 5-Rehab Center, 6-Nursing Home
Hospice Status, Current Month	CMS Hospice file[*2]	Yes, No, Unknown
AKI	72x Bill	Acute Kidney Injury (see codes in following table)
Hospital Referral Region (HRR)[1]	CMS data sources	Numerical Value
Facility CCN#	EQRS/CROWNWeb	CROWNWeb Facility Unique Identifier

The table lists the data elements required to identify the measure exclusions.

AKI Codes:

Condition Code	CPT Code	ICD-10 Codes	Description
84	*	*	Dialysis for Acute Kidney Injury
*	G0491	*	Dialysis procedure at a Medicare certified ESRD facility for Acute Kidney Injury without ESRD
*	*	N17.0	Acute kidney failure with tubular necrosis
*	*	N17.1	Acute kidney failure with acute cortical necrosis
*	*	N17.2	Acute kidney failure with medullary necrosis
*	*	N17.8	Other acute kidney failure
*	*	N17.9	Acute kidney failure, unspecified
*	*	T79.5XXA	Traumatic anuria, initial encounter
*	*	T79.5XXD	Traumatic anuria, subsequent encounter
*	*	T79.5XXS	Traumatic anuria, sequela
*	*	N99.0	Post-procedural (acute)(chronic) renal failure

The table lists AKI Condition Codes, CPT Codes, ICD-10 Codes and descriptions.

*Cell intentionally left blank.

References:

1. In recognition of the structure of the dialysis market, if a company owns multiple facilities in a given Hospital Referral Region (HRR), it would report an aggregated score for all facilities located within the HRR owned wholly or in part by the company.

[Response Ends]

sp.19. Provide all information required to stratify the measure results, if necessary.

Include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate. Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format in the Data Dictionary field.

[Response Begins]

The following stratification variables are applied to the KCQA Home Dialysis Rate Measure scores:

- Age (0-<18 years, 18-<25, 25-<35, 35-<45, 45-<55, 55-<65, 65-<75, 75-<85, 85+)
- Gender (Male, Female)
- Race (White, Black, Other)
- Ethnicity (Hispanic, Non-Hispanic)
- Dual-eligibility status (Yes, No)

The following data elements are required to stratify the measure:

Data Element	Primary Data Source(s)	Values
Reporting Year	EQRS/CROWNWeb	Clinical Year (YYYY)
Dialysis Setting	EQRS/CROWNWeb	1-Home, 2-Dialysis Facility/Center, 3-SNF/Long Term Care Facility
Dialysis Modality	EQRS/CROWNWeb	Hemodialysis, CAPD, CCPD, Other
Date of Birth	EQRS/CROWNWeb	Date
Gender	EQRS/CROWNWeb	M, F
Race	EQRS/CROWNWeb	1 - American Indian/Alaska Native, 2 - Asian, 3 - Black or African American, 4 - White, 6 - Native Hawaiian or Other Pacific Islander
Ethnicity	EQRS/CROWNWeb	6 - Non-Hispanic or Latino, 7 - Hispanic or Latino
Insurance	EQRS/Medical Evidence Form (CMS-2728)	Medicare, Medicaid, Employer Group Health Insurance, VA, MA, Other, None
Hospital Referral Region (HRR)[1]	CMS data sources	Numerical Value
Facility CCN#	EQRS/CROWNWeb	CROWNWeb Facility Unique Identifier

The table lists the data elements required to identify the measure stratification variables.

References:

1. In recognition of the structure of the dialysis market, if a company owns multiple facilities in a given Hospital Referral Region (HRR), it would report an aggregated score for all facilities located within the HRR owned wholly or in part by the company.

Clarification Requested by NQF: Please clarify if ethnicity is exhaustive for all patients? Or will options 1-5 in CROWNWeb be able to be chosen instead of 6/7? It appears that this is the case in the demographic table in 2a.06, but 2b. 09 appears to show this is missing for 4% of patients. Please clarify.

Response: Both race and ethnicity should be entered in CROWNWeb for all patients. However, as indicated in our testing data (see 2b.09), approximately 0.4% of patient-months in our measurement year were found to be missing

race data and 2.6% were missing ethnicity data. Thus while missing data were small, neither race nor ethnicity data are entirely exhaustive for all patients.

[Response Ends]

sp.20. Is this measure adjusted for socioeconomic status (SES)?

[Response Begins]

No

[Response Ends]

sp.21. Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.

[Response Begins]

Stratification by risk category/subgroup (specify number of risk factors)

[Stratification by risk category/subgroup (specify number of risk factors) Please Explain]

Measure results are stratified by 5 risk factor groups: age, gender, race, ethnicity, dual-eligibility.

[Response Ends]

sp.22. Select the most relevant type of score.

Attachment: If available, please provide a sample report.

[Response Begins]

Rate/proportion

[Response Ends]

sp.23. Select the appropriate interpretation of the measure score.

Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score

[Response Begins]

Better quality = Higher score

[Response Ends]

sp.24. Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

[Response Begins]

KCQA HOME DIALYSIS RATE CALCULATION ALGORITHM DIAGRAM

Note: 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 ESRD facilities located within the HRR owned wholly or in part by the company.

[Response Ends]

sp.27. If measure testing is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

Examples of samples used for testing:

• Testing may be conducted on a sample of the accountable entities (e.g., hospital, physician). The analytic unit specified for the particular measure (e.g., physician, hospital, home health agency) determines the sampling strategy for scientific acceptability testing.

• The sample should represent the variety of entities whose performance will be measured. The 2010 Measure Testing Task Force recognized that the samples used for reliability and validity testing often have limited generalizability because measured entities volunteer to participate. Ideally, however, all types of entities whose performance will be measured should be included in reliability and validity testing.

• The sample should include adequate numbers of units of measurement and adequate numbers of patients to answer the specific reliability or validity question with the chosen statistical method.

• When possible, units of measurement and patients within units should be randomly selected.

[Response Begins]

N/A; measure not based on a sample.

[Response Ends]

sp.30. Select only the data sources for which the measure is specified.

[Response Begins]

Electronic Health Data

Electronic Health Records

[Response Ends]

sp.31. Identify the specific data source or data collection instrument.

For example, provide the name of the database, clinical registry, collection instrument, etc., and describe how data are collected.

[Response Begins]

The measure is intended for use by CMS in its ESRD Quality Reporting System (EQRS), encompassing an extensive national ESRD patient database primarily based on the Renal Management System (REMIS), EQRS facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form and CMS-2746 Death Notification Form), the Medicare Enrollment Database, Medicare claims data, transplant data from the Scientific Registry of Transplant Recipients (SRTR), and data from the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment [ASPEN]), and Dialysis Facility Compare. The database is comprehensive for patients not enrolled in Medicare Advantage. Medicare Advantage patients are included in all EQRS sources, but their Medicare payment records are limited to inpatient claims. Non-Medicare patients are included in all sources except for the Medicare payment records. Tracking by dialysis provider, treatment modality, and treatment setting is available for all patients, including those with only partial or no Medicare coverage.

[Response Ends]

sp.32. Provide the data collection instrument.

[Response Begins]

No data collection instrument provided

[Response Ends]

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate fields in the Scientific Acceptability sections of the Measure Submission Form.

- Measures must be tested for all the data sources and levels of analyses that are specified. If there is more than one set of data specifications or more than one level of analysis, contact NQF staff about how to present all the testing information in one form.
- All required sections must be completed.
- For composites with outcome and resource use measures, Questions 2b.23-2b.37 (Risk Adjustment) also must be completed.
- If specified for multiple data sources/sets of specifications (e.g., claims and EHRs), Questions 2b.11-2b.13 also must be completed.
- An appendix for supplemental materials may be submitted (see Question 1 in the Additional section), but there is no guarantee it will be reviewed.
- Contact NQF staff with any questions. Check for resources at the Submitting Standards webpage.
- For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for the 2021 Measure Evaluation Criteria and Guidance.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF's evaluation criteria for testing.

2a. Reliability testing demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument based measures (including PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure;

AND

If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

2b3. For outcome measures and other measures when indicated (e.g., resource use):

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; 14,15 and has demonstrated adequate discrimination and calibration
- rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful 16 differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

2b6. Analyses identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias.

2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:

2c1. the component measures fit the quality construct and add value to the overall composite while achieving the related objective of parsimony to the extent possible; and

2c2. the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.

(if not conducted or results not adequate, justification must be submitted and accepted)

Definitions

Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.

Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

Risk factors that influence outcomes should not be specified as exclusions.

With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v.$5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous (Year) Submission:

Testing from the previous submission here.

2a.01. Select only the data sources for which the measure is tested.

[Response Begins]

Electronic Health Data

Electronic Health Records

[Response Ends]

2a.02. If an existing dataset was used, identify the specific dataset.

The dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

[Response Begins]

The Home Dialysis Rate Measure was tested using data from two KCQA member Large Dialysis Organizations (LDOs), each with the capacity to provide retrospective analyses of patient- and facility-level data as submitted to CMS's EQRS/CROWNWeb. All pertinent data from all eligible patients (i.e., adult and pediatric in-center and home hemodialysis and peritoneal dialysis) in all facilities of the participating organizations during the testing period were included in our testing data.

Of note:

- To account for home dialysis–only facilities within a Hospital Referral Region (HRR), particularly if a parent company sends its home dialysis patients to such a provider, the measure allows for aggregation of facilities owned by the same company within a given HRR. Specifically, a subsidiary facility's Home Dialysis Rate is aggregated to the facility's aggregation group, which includes all dialysis facilities owned in whole or in part by the same legal entity ("Parent Organization") located in the HRR in which the facility is located.
- Data for measure testing were collected at the facility level, then aggregated to the parent DO HRR level (where applicable). Throughout this form, testing results are presented at both the facility-level and the HRR-level; this approach allows for NQF assessment of how "independent" facilities that are not subsidiaries of any parent company might perform. Additionally, HRR data are presented at the DO-level only where important/necessary to illustrate differences across the DOs; otherwise, the "overall" HRR-level data across both DOs are presented to preserve company anonymity (also see the following bullet point).
- To preserve anonymity, data are presented as coming from Dialysis Organization (DO) 1 and 2, where applicable. This nomenclature is random and is randomly scrambled throughout the measure submission documents such that DO 1 in one section might become DO 2 in another section, and vice versa.

[Response Ends]

2a.03. Provide the dates of the data used in testing.

Use the following format: "MM-DD-YYYY - MM-DD-YYYY"

[Response Begins]

01-01-2021 – 12-31-2021

[Response Ends]

2a.04. Select the levels of analysis for which the measure is tested.

Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

Other (specify)

[Other (specify) Please Explain]

To account for home dialysis–only facilities within a Hospital Referral Region (HRR), particularly if a parent company sends its home dialysis patients to such a provider, the measure allows for aggregation of facilities owned by the same company within a given HRR. Specifically, a subsidiary facility's Home Dialysis Rate is aggregated to the facility's aggregation group, which includes all dialysis facilities owned in whole or in part by the same legal entity ("Parent Organization") located in the HRR in which the facility is located.

[Response Ends]

2a.05. List the measured entities included in the testing and analysis (by level of analysis and data source).

Identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample.

[Response Begins]

Data were collected at the dialysis facility level; to account for home dialysis–only facilities, performance was then aggregated by parent Dialysis Organization (DO) within Hospital Referral Regions (HRRs), as applicable. All 5,781 facilities in the two participating LDOs were included in the analysis, comprising 295 HRRs, with 267 HRRs for each of the participating DOs.

The distribution of facility size (expressed as number of patients) is as follows:

N of Facilities	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
5,781	91	52	1	53	82	117	438	34	48	59	70	94	109	128	158

The table illustrates the Distribution and Deciles of Facility Size

For the 295 HRRs included in the analysis, the mean number of patients across each of the DO's 267 aggregated HRR units was 8,365 per HRR, with a range of 74 to 124,143.

[Response Ends]

2a.06. Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.

If there is a minimum case count used for testing, that minimum must be reflected in the specifications.

[Response Begins]

The number and percent of all patients and patient-months across all participating facilities that were included in the analysis are displayed in the following table by age, sex, race, ethnicity, and dual eligible groups:

*	Patients	%	Patient-Months	%
Total	**463,821**	**100.0**	**4,348,920**	**100.0**
Age	*	*	*	*
0-<18	554	0.1	4,054	0.1
18-<25	3,471	0.7	30,058	0.7
25-<35	18,051	3.9	168,349	3.9
35-<45	38,848	8.4	371,073	8.5
45-<55	74,850	16.1	719,804	16.6
55-<65	115,485	24.9	1,091,927	25.1
65-<75	121,712	26.2	1,131,992	26.0
75-<85	72,662	15.7	665,215	15.3
>=85	18,188	3.9	166,448	3.8
Sex	*	*	*	*
Female	194,869	42.0	1,826,680	42.0
Male	268,952	58.0	2,522,240	58.0
Race	*	*	*	*
White	271,139	58.5	2,493,562	57.3
Black	158,021	34.1	1,523,363	35.0
Other	34,661	7.5	331,995	7.6
Ethnicity	*	*	*	*
Non-Hispanic	383,086	82.6	3,567,401	82.0
Hispanic	80,735	17.4	781,519	18.0
Dual Eligible	*	*	*	*
No	337,000	72.7	3,075,327	70.7
Yes	126,821	27.3	1,273,593	29.3

The table illustrates Patient's demographic Characteristics

* Cell intentionally left blank.

Clarification Requested by NQF: From sp.19: Please clarify if ethnicity is exhaustive for all patients? Or will options 1-5 in CROWNWeb be able to be chosen instead of 6/7? It appears that this is the case in the demographic table in 2a.06, but 2b. 09 appears to show this is missing for 4% of patients. Please clarify.

Response: Both race and ethnicity should be entered in CROWNWeb for all patients. However, as indicated in our testing data (see 2b.09), approximately 0.4% of patient-months in our measurement year were found to be missing race data and 2.6% were missing ethnicity data. Thus while missing data were small, neither race nor ethnicity data are entirely exhaustive for all patients.

[Response Ends]

2a.07. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing.

[Response Begins]

There are no differences in the data for different aspects of testing.

[Response Ends]

2a.08. List the social risk factors that were available and analyzed.

For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

[Response Begins]

Patient-level social risk factors that were available and analyzed include the following:

- Age (0-<18 years, 18-<25, 25-<35, 35-<45, 45-<55, 55-<65, 65-<75, 75-<85, 85+)
- Gender
- Race (White, Black, Other)
- Ethnicity (Hispanic, Non-Hispanic)
- Dual-eligibility status (Yes, No)

[Response Ends]

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.09 check patient or encounter-level data; in 2a.010 enter "see validity testing section of data elements"; and enter "N/A" for 2a.11 and 2a.12.

2a.09. Select the level of reliability testing conducted.

Choose one or both levels.

[Response Begins]

Accountable Entity Level (e.g., signal-to-noise analysis)

[Response Ends]

2a.10. For each level of reliability testing checked above, describe the method of reliability testing and what it tests.

Describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used.

[Response Begins]

To assess signal-to-noise, we employed the beta-binomial model as described by JL Adams in "The Reliability of Provider Profiling."[1] Using the techniques detailed in that document, we estimated the facility-to-facility variance (the signal) and the within-facility variance (the noise). The same was done at the HRR level. The ratio of these estimates then produced an estimate of the reliability at each facility and HRR aggregate unit, where a reliability of 0 implies that all variability is due to measurement error and a reliability of 1 indicates that all variability is due to real differences in performance:

$$reliability = \frac{\sigma^2_{provider-to-}}{\sigma^2_{provider-to-provi}}$$

$$\sigma^2_{provider-to-provider} = \frac{\alpha\beta}{(\alpha+\beta+1)}$$

$$\sigma^2_{error} = \frac{p(1-p)}{n}$$

The distribution of reliability estimates across all facilities and HRR aggregate units was then examined, as below.

References:

1. Adams, JL. *The reliability of provider profiling: A tutorial.* RAND Health, 2009.

[Response Ends]

2a.11. For each level of reliability testing checked above, what were the statistical results from reliability testing?

For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis,

more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, NQF Measure Evaluation Criteria).

[Response Begins]

FACILITY LEVEL

Overall facility-level reliability scores are illustrated in the following table:

*	N of facilities	Mean	STD	Min	10th Pctl	Q1	Median	Q3	90th Pctl	Max	Alpha	Beta
Overall	5781	0.9987	0.0058	0.8224	0.9967	0.9983	1.0000	1.0000	1.0000	1.0000	0.0987	0.5209

The table illustrates the Facility-Level Measurement Year Reliability

* Cell intentionally left blank.

To empirically assess for the need to exclude small facilities, we also calculated reliability scores by facility size, measured by the average number of patients per facility across the measurement year:

By facility size (Ns of patients per facility)	N of facilities	Mean	STD	Min	10th Pctl	Q1	Median	Q3	90th Pctl	Max	Alpha	Beta
< 25	269	0.9963	0.0136	0.9033	0.9941	0.9997	1.0000	1.0000	1.0000	1.0000	0.0507	0.1362
25-< 50	990	0.9987	0.0027	0.9609	0.9950	0.9990	1.0000	1.0000	1.0000	1.0000	0.0558	0.3009
50-<80	1,510	0.9987	0.0021	0.9793	0.9953	0.9978	1.0000	1.0000	1.0000	1.0000	0.0781	0.4715
80-<120	1,634	0.9986	0.0018	0.9869	0.9959	0.9973	1.0000	1.0000	1.0000	1.0000	0.1094	0.7275
120+	1,378	0.9989	0.0011	0.9945	0.9974	0.9981	0.9990	1.0000	1.0000	1.0000	0.1839	0.9403

The table illustrates the Measurement Year Reliability by Facility Szie

Again, all scores, regardless of facility size, are greater than 0.99.

Finally, to demonstrate that our reliability scores are not a function of the non-independence of consecutive patient-month observations across patients, we also calculated a "sample-size adjusted" reliability for each individual month using total yearly patient-months in the measurement error for each facility, but holding the variance between facilities the same. When calculating a facility monthly within-variance, the "n" in the above formula is the total patient-months for the total measurement year instead of the total patient-months in the corresponding month. As can be seen, the "sample-size adjusted" reliability each month is very close to the reliability for the measurement year overall**:**

*	N of facilities	Mean	STD	Min	10th Pctl	Q1	Median	Q3	90th Pctl	Max	Alpha	Beta
Measurement Year	**5781**	**0.9987**	**0.0058**	**0.8224**	**0.9967**	**0.9983**	**1.0000**	**1.0000**	**1.0000**	**1.0000**	**0.0987**	**0.5209**
By Measurement Month:	*	*	*	*	*	*	*	*	*	*	*	*
Month 1	5709	0.9864	0.0278	0.3781	0.9607	0.9791	1.000	1.000	1.000	1.000	0.1240	0.6487
Month 2	5724	0.9870	0.0245	0.3822	0.9608	0.9795	1.000	1.000	1.000	1.000	0.1219	0.6316
Month 3	5726	0.9868	0.0248	0.3811	0.9603	0.9790	1.000	1.000	1.000	1.000	0.1235	0.6393
Month 4	5729	0.9869	0.0245	0.5094	0.9606	0.9793	1.000	1.000	1.000	1.000	0.1243	0.6423
Month 5	5733	0.9870	0.0245	0.3829	0.9607	0.9791	1.000	1.000	1.000	1.000	0.1226	0.6320
Month 6	5735	0.9864	0.0288	0.3803	0.9600	0.9792	1.000	1.000	1.000	1.000	0.1237	0.6420
Month 7	5736	0.9868	0.0275	0.3856	0.9607	0.9798	1.000	1.000	1.000	1.000	0.1223	0.6241
Month 8	5727	0.9867	0.0276	0.3841	0.9602	0.9793	1.000	1.000	1.000	1.000	0.1228	0.6294
Month 9	5716	0.9871	0.0274	0.3910	0.9619	0.9801	1.000	1.000	1.000	1.000	0.1213	0.6075
Month 10	5706	0.9868	0.0279	0.3879	0.9612	0.9799	1.000	1.000	1.000	1.000	0.1226	0.6192
Month 11	5687	0.9872	0.0249	0.3898	0.9614	0.9799	1.000	1.000	1.000	1.000	0.1223	0.6135
Month 12	5677	0.9870	0.0249	0.3887	0.9613	0.9796	1.000	1.000	1.000	1.000	0.1223	0.6162

The table illustrates the Facility-Level Measurement Month Reliability

* Cell intentionally left blank.

The reliability score for each individual month, wherein each patient can contribute only a single observation to the denominator and numerator, remains excellent at > 0.98 for all twelve months.

HRR LEVEL

We also examined reliability at aggregate HRR unit level. The mean reliability for yearly measurement data was 0.994 or greater across all aggregate units:[1]

*	N of HRR	Mean	STD	Min	10th Pctl	Q1	Median	Q3	90th Pctl	Max	Alpha	Beta
Overall	295	0.9940	0.0084	0.9417	0.9853	0.9932	0.9968	0.9987	0.9994	1.0000	4.7049	23.7119
DO 1	267	0.9939	0.0098	0.9200	0.9853	0.9932	0.9975	0.9990	0.9995	1.0000	2.3993	12.2235
DO 2	267	0.9966	0.0058	0.9561	0.9919	0.9965	0.9986	0.9993	0.9997	1.0000	1.5478	6.7195

The table illustrates the HRR-Level Measurement Year Reliability, by Parent Organizations

*Cell intentionally left blank.

Monthly reliability was assessed at the overall HRR-level and was found to be slightly decreased compared to monthly reliability at facility-level, which may be due to smaller sample size using monthly data and/or decreased variation between HRRs (compared to variation between facilities). However, values for all months remain at greater than or equal to 0.92.

Measurement month	N of HRR	Mean	STD	Min	10th Pctl	Q1	Median	Q3	90th Pctl	Max	Alpha	Beta
Month 1	295	0.9228	0.0869	0.5262	0.8013	0.9060	0.952	0.980	0.991	1.000	6.1600	31.6102
Month 2	295	0.9220	0.0861	0.5045	0.8048	0.9007	0.951	0.980	0.991	1.000	6.3246	32.3857
Month 3	295	0.9226	0.0851	0.4962	0.8043	0.9020	0.952	0.980	0.991	1.000	6.2684	32.1188
Month 4	295	0.9202	0.0875	0.4772	0.8020	0.8979	0.951	0.979	0.991	1.000	6.5293	33.3392
Month 5	295	0.9187	0.0885	0.4845	0.8009	0.8966	0.949	0.978	0.990	1.000	6.6434	33.8215
Month 6	295	0.9216	0.0861	0.5067	0.8058	0.8988	0.951	0.980	0.991	1.000	6.4276	32.7951
Month 7	295	0.9299	0.0788	0.5232	0.8291	0.9112	0.956	0.982	0.992	1.000	5.7752	29.0032
Month 8	295	0.9305	0.0786	0.5212	0.8263	0.9130	0.957	0.982	0.992	1.000	5.7113	28.5999
Month 9	295	0.9309	0.0783	0.5219	0.8287	0.9127	0.957	0.982	0.992	1.000	5.6478	27.9725
Month 10	295	0.9281	0.0814	0.4817	0.8256	0.9095	0.955	0.981	0.992	1.000	5.8654	29.2224
Month 11	295	0.9270	0.0823	0.4991	0.8292	0.9074	0.955	0.981	0.992	1.000	5.9460	29.4818
Month 12	295	0.9257	0.0827	0.5044	0.8127	0.9014	0.955	0.980	0.992	1.000	6.0868	30.0959

The table illustrates the Overall HRR-Level Measurement Month Reliability

References:

1. To preserve anonymity, data are presented as coming from Dialysis Organization (DO) 1 and 2, where applicable. This nomenclature is random and is randomly scrambled throughout the measure submission documents such that DO 1 in one section might become DO 2 in another section, and vice versa.

[Response Ends]

2a.12. Interpret the results, in terms of how they demonstrate reliability.

(In other words, what do the results mean and what are the norms for the test conducted?)

[Response Begins]

Signal-to-noise reliability is excellent at both the facility level (independent of size) and the aggregate HRR unit levels. We've also demonstrated that these findings are not a function of the non-independence of consecutive patient-month observations.

[Response Ends]

2b.01. Select the level of validity testing that was conducted.

[Response Begins]

Accountable Entity Level (e.g. hospitals, clinicians)

Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)

[Response Ends]

2b.02. For each level of testing checked above, describe the method of validity testing and what it tests.

Describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used.

[Response Begins]

Face Validity of the measure was also analyzed. Per NQF guidance,[1] face validity of the measure was assessed through a systematic and transparent process by identified experts. Specifically, experts in the field of ESRD and dialysis care and uninvolved in the KCQA measure development process were identified from Kidney Care Partner (KCP) member organizations and were invited to participate in a formal face validity assessment of the KCQA Home Dialysis Measures. The resulting panel of nine consisted of individuals from five healthcare providers, two dialysis facilities, and three manufacturers groups.[2] Panel members were provided the detailed measure specifications (and measure scores and performance distributions) and were asked to complete a formal survey explicitly inquiring whether they believe the measures will accurately assess the intended criterion. Individuals responded to the following two questions for each measure and for the measure set as a whole:

- How likely is it that the measure score(s) provides a fair and accurate reflection of the quality of care provided in this area? (highly unlikely; unlikely; neither likely nor unlikely; likely; highly likely)
- What is the likelihood that the measure score(s) can be used to effectively distinguish real differences in performance between providers in this area? (highly unlikely; unlikely; neither likely nor unlikely; likely; highly likely)

NOTE: KCQA is in the process of polling additional experts to broaden our Face Validity Panel, in particular with additional patients to address the SMP's prior concerns in this regard. The documents will be updated ASAP, well in advance of the SMP's review.

References:

1. NQF Measure Evaluation Criteria.
2. The Expert Panel List is included in the KCQA Supplemental Materials File.

[Response Ends]

2b.03. Provide the statistical results from validity testing.

Examples may include correlations or t-test results.

[Response Begins]

Face Validity: There was significant agreement among Expert Panel members that scores from the Home Dialysis Rate Measure as specified provides a fair and accurate assessment of quality and effectively distinguishes differences in performance between providers:

- 88.89% of Expert Panel Members (n=8 of 9) agreed it is highly likely or likely that the measure score will provide an accurate reflection of quality.
- 88.89% (8 of 9) agreed it is highly likely or likely that the measure score will effectively distinguish real differences in performance between providers.

For the measure set, as a whole:

- 88.89% of Expert Panel Members (n=8 of 9) agreed it is highly likely or likely that the measure scores for the paired set will provide an accurate reflection of quality.
- 88.89% (8 of 9) agreed it is highly likely or likely that the measure scores for the paired set will effectively distinguish real differences in performance between providers.

The single panelist who indicated "unlikely" to the above questions provided the following comment:

> *"With minimal patient exclusion criteria, I am concerned that this measure will end up being more reflective of a provider's patient population than the quality of care that provider delivers. I recognize that there is some stratification, but I don't think it goes far enough, and there are so many intangibles involved when determining a patient's appropriateness for home dialysis that make getting this measure right so difficult."*

This feedback was shared with the Steering Committee; the Committee acknowledged the commenter's concerns, but agreed that patients' appropriateness for home dialysis had been considered and extensively debated throughout the measurement development process, leading to the recommendation that the Home Dialysis Rate measure be paired with the Home Dialysis Retention Measure. Specifically, the KCQA Home Dialysis Workgroup and Steering Committee shared the concern that the recently launched ESRD Treatment Choices (ETC) Payment Model has the potential to incentivize a rapid rise in the use of home dialysis and increased technique failure rates. It may also subject many patients to a treatment modality for which they have not received adequate education or training, and may even inadvertently result in infringement on patient choice. To address such concerns, KCQA's Home Dialysis Measure Set has been developed and designed 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 rate measure were implemented alone, minimizing the potential adverse consequences of unchecked home dialysis growth. 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.

[Response Ends]

2b.04. Provide your interpretation of the results in terms of demonstrating validity. (i.e., what do the results mean and what are the norms for the test conducted?)

[Response Begins]

There was a high level of agreement among Expert Panel Members that scores from the Home Dialysis Rate Measure (and measure set) as specified will provide an accurate assessment of quality and will effectively distinguish differences in performance between providers. Our interpretation of these results is that both the Rate Measure and the measure set have substantial face validity.

[Response Ends]

2b.05. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified.

Describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided in Importance to Measure and Report: Gap in Care/Disparities.

[Response Begins]

Descriptive statistics for the annual performance measure scores were constructed, including the mean, median, range, standard deviation, and deciles of scores across the measured entities. First, we examined the overall spread of performance scores by calculating the distributions and deciles of the measurement year scores, overall and by facility size and at the aggregate HRR unit levels. Second, we calculated the cumulative frequency and percentage of facilities included by different ranges of measurement year scores. We also examined the number of facilities identified for different ranges of measurement year scores.

[Response Ends]

2b.06. Describe the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.

Examples may include number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined.

[Response Begins]

FACILITY-LEVEL ANALYSES:

Distribution and deciles of performance score, overall and by facility size:

By Facility Size (N of patients)	N of facilities	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Overall: all facilities	5,781	14.57	25.12	0.00	0.00	0.16	20.02	100.00	0.00	0.00	0.00	0.00	9.03	16.77	23.99	38.13
Overall: exclude facility size <25 patients	5,512	13.98	23.91	0.00	0.00	0.18	19.85	100.00	0.00	0.00	0.00	0.00	9.18	16.75	23.67	36.46
< 25	270	26.68	41.17	0.00	0.00	0.00	41.54	100.00	0.00	0.00	0.00	0.00	1.06	20.12	96.48	100.00
25-< 50	990	14.80	30.23	0.00	0.00	0.00	13.93	100.00	0.00	0.00	0.00	0.00	0.00	8.93	20.21	94.44
50-<80	1,510	12.65	24.95	0.00	0.00	0.00	16.48	100.00	0.00	0.00	0.00	0.00	0.32	11.81	20.52	35.02
80-<120	1,634	12.66	20.99	0.00	0.00	0.15	19.23	100.00	0.00	0.00	0.00	0.00	9.75	16.46	22.72	33.73
120+	1,378	16.41	20.40	0.00	0.00	12.11	24.88	99.89	0.00	0.00	0.05	5.96	17.30	22.10	27.84	37.87

The table illustrates the Distribution and Deciles of Performance Scores, Overall and by Facility Size

The distribution of facility-level measurement year scores is summarized below:

Score range	N	%	Cumulative N	Cumulative %
0	2711	46.89	2,711	46.9
>0-< 1%	451	7.8	3,162	54.7
1-<10%	369	6.38	3,531	61.1
10-<15%	380	6.57	3,911	67.6
15-<20%	421	7.28	4,332	74.9
20-<25%	346	5.98	4,678	80.9
25-<30%	264	4.57	4,942	85.5
30-<35%	173	2.99	5,115	88.5
35-<40%	128	2.21	5,243	90.7
>=40%	539	9.32	5,782	100.0

The table illustrates the Facility-Level Performance Distribution

To demonstrate the statistical significance of the spread, we performed the following analyses among 3,071 facilities (out of 5,781) with a non-zero performance score.[1] The overall weighted mean performance score was

24.5% with the facility size as the weight (this is the national percent of home dialysis among those facilities with at least one home dialysis patient-month). We call this the national norm. The distribution of performance scores among the 3,071 facilities are illustrated below:

Deciles	**Min**	**5th**	**10th**	**20th**	**30th**	**40th**	**50th**	**60th**	**70th**	**80th**	**90th**	**95th**	**Max**
Performance score, %	0.05	0.15	0.27	6.47	11.33	15.46	19.06	22.96	28.29	36.79	95.33	99.28	100.00

The table illustrates the Distribution of Facility Performance Scores

We then grouped the facilities based on deciles of performance score and calculated the 95% confidence interval (CI) of the performance score for each facility. If the 95% CI of a facility does not include the national norm, then the performance score of the facility was statistically different from the national norm, either above or below the norm. As a result, we found that:

- Among the 615 facilities with a score between 0.05% (min) and 6.47% (the 20th decile), all facilities had 95% CIs below the norm.
- Among the 308 facilities with a score from >95.3% (the 90th decile) to 100% (max), all facilities had 95% CIs above the norm.
- Among 614 facilities with a score from >36.8% (the 80th decile) to 100% (max), 613 had 95% CIs above the norm. Only one facility included the national norm in the 95% CI.

These results indicate that performance scores can identify statistically significant and practically meaningful differences in performance between facilities. The high reliability score also indicates that most variability is due to real differences in performance between facilities.

The cumulative frequency and percentage of facilities covered by ranges of measurement scores are summarized in the following bar graphs:

HRR-LEVEL ANALYSES:

Distribution and deciles of aggregate HRR unit performance scores:[2]

*	# HRRs	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Overall	295	16.58	6.57	0.00	12.52	16.00	19.51	48.02	9.70	11.94	13.55	14.79	17.22	18.33	20.35	24.50
DO 1	267	17.26	11.90	0.00	11.58	15.54	19.43	100.00	7.78	10.81	12.71	14.40	16.78	18.35	20.64	26.20
DO 2	267	16.37	9.21	0.00	11.23	14.87	20.01	97.30	7.52	10.41	12.10	13.79	16.89	18.61	21.20	26.32

The table illustrates the Distribution and Deciles of HRR-Level Performance Scores, by Parent Organization

*Cell intentionally left blank.

The distribution of overall HRR-level measurement year scores across both DOs is summarized below:

Score range	N	%	Cumulative N	Cumulative %
< 1%	2	0.68	2	0.7
1-<10%	31	10.51	33	11.2
10-<15%	92	31.19	125	42.4
15-<20%	101	34.24	226	76.6
20-<25%	42	14.24	268	90.9
25-<30%	14	4.75	282	95.6
30-<35%	8	2.71	290	98.3
>=35%	5	1.69	295	100.0

The table illustrates the Disbribution of Overall HRR Performance

The cumulative frequency and percentage of overall HRRs covered by ranges of measurement scores are summarized in the following bar graphs:

References/Notes:

1. In the current data, there are a large number of facilities with 0 home dialysis patients; such facilities were included in the "low" performance group.
2. To preserve anonymity, data are presented as coming from Dialysis Organization (DO) 1 and 2, where applicable. This nomenclature is random and is randomly scrambled throughout the measure submission documents such that DO 1 in one section might become DO 2 in another section, and vice versa.

[Response Ends]

2b.07. Provide your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities.

In other words, what do the results mean in terms of statistical and meaningful differences?

[Response Begins]

As above, we've demonstrated that performance scores can identify statistically significant and practically meaningful differences in performance between facilities. The high reliability score also indicates that most variability is due to real differences in performance between facilities.

Likewise, our results show that there are statistical and practical differences in performance at both the facility-level and the aggregate HRR unit-levels, with a significant spread demonstrated between minimum and maximum scores, mean/median and maximum scores, and various deciles of performance.

[Response Ends]

2b.08. Describe the method of testing conducted to identify the extent and distribution of missing data (or non-response) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing data minimizes bias.

Describe the steps—do not just name a method; what statistical analysis was used.

[Response Begins]

Neither missing data nor non-response were an issue with the measures because the data used are routinely collected by facilities. Data regarding the number of patients each month at a facility, the number on home dialysis, and the number of consecutive months on a given modality are readily available and typically not missing. Additionally, patient information on age, sex, race, ethnicity, and dual-eligibility status is also well documented and easily retrievable.

[Response Ends]

2b.09. Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.

For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).

[Response Begins]

During measure testing we learned that facilities do not always have ready access to data on hospice enrollment and that collection of this data element varied by both parent dialysis organization and by individual facility. As affected facilities were unable to determine the frequency with which this data element was “missing” because it is not routinely or reliably captured in their records, we do not have a firm grasp on the missingness of this data element and believe our observed percent of patient-months excluded secondary to hospice enrollment (0.01%) is an underestimate. However, we believe these same patients are captured in other exclusions (i.e., nursing home/LTCF residence, discontinuation of dialysis, and discharge secondary to death) and that this issue thus does not appreciably impact our analyses.

Similarly, capture of the nursing home/LTCF residence exclusion was variable, this time largely across parent DO. As a result, we again speculate that our observed percent patient-months excluded here (2.8%) is likely an underestimate. However, if we were for caution’s sake to err toward the highest nursing home/LTCF exclusion rate reported during the measurement year (5.5%), our final denominator would decrease from 4,467,488 patient-months to 4,334,960 patient-months, increasing our overall facility-level score from 14.6% to approximately 14.9%, a difference of only 0.3%.

We thus believe that the inability to reliably capture all nursing home/LTCF and hospice exclusions during measure testing did not appreciably impact our testing results. We also again note that the KCQA Home Dialysis Rate Measure is intended for use by CMS in its ESRD Quality Reporting System (EQRS). During testing, we did not have access to the complete scope and range of data available to CMS within its national ESRD patient database—most notably, we do not have ready access to data from CMS's Hospice Files or Nursing Home Minimum Data Set. If adopted by CMS for use in its ESRD accountability programs, the issues described above will be virtually eliminated.

Other data elements required to calculate the measure were readily available, but we did encounter some missingness among our stratification variables:

Variable	N of Patient-Months	%	N of Patients	%
Missing age	30	0.0	6	0.0
Missing sex	3	0.0	3	0.0
Missing race	17,278	0.4	5,632	1.2
Missing ethnicity	117,185	2.6	19,409	4.0
Missing dual eligibility	0	0.0	0	0.0

The table illustrates Missing Stratification Variables identified during testing

*Cell intentionally left blank.

As above, missing values were quite small and had little effect on facility-level scores. When patient-months were excluded from the denominator due to missing values in stratification variables, mean facility-level performance dropped by only 0.09% (from 14.58% to 14.49%) after excluding missing values. The median remained the same at 0.16%.

Likewise, missing stratification data had little impact on HRR-level performance, with scores dropping only 0.11% when patient-months with missing data were excluded from the denominator:

*	N of HRRs	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Missing Values Included	295	16.58	6.57	0.00	12.52	16.00	19.51	48.02	9.70	11.94	13.55	14.79	17.22	18.33	20.35	24.50
Missing Values Excluded	295	16.47	6.62	0.00	12.27	16.00	19.38	48.02	9.70	11.81	13.38	14.71	16.97	18.34	20.33	24.42

The table illustrates the Impact of Missing Data on Overall HRR-Level Scores

*Cell intentionally left blank.

Clarification Requested by NQF: From sp.19: Please clarify if ethnicity is exhaustive for all patients? Or will options 1-5 in CROWNWeb be able to be chosen instead of 6/7? It appears that this is the case in the demographic table in 2a.06, but 2b. 09 appears to show this is missing for 4% of patients. Please clarify.

Response: Both race and ethnicity should be entered in CROWNWeb for all patients. However, as indicated in our testing data (see 2b.09), approximately 0.4% of patient-months in our measurement year were found to be missing race data and 2.6% were missing ethnicity data. Thus while missing data were small, neither race nor ethnicity data are entirely exhaustive for all patients.

[Response Ends]

2b.10. Provide your interpretation of the results, in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.

In other words, what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis was conducted, justify the selected approach for missing data.

[Response Begins]

Missing data are rare, have minimal effect on the overall performance, and do not introduce significant bias. Reporting months with missing values are thus not excluded from the measure.

[Response Ends]

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) OR to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eCQMs). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

2b.11. Indicate whether there is more than one set of specifications for this measure.

[Response Begins]

No, there is only one set of specifications for this measure

[Response Ends]

2b.12. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications.

Describe the steps—do not just name a method. Indicate what statistical analysis was used.

[Response Begins]

[Response Ends]

2b.13. Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.

Examples may include correlation, and/or rank order.

[Response Begins]

[Response Ends]

2b.14. Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.

In other words, what do the results mean and what are the norms for the test conducted.

[Response Begins]

[Response Ends]

2b.15. Indicate whether the measure uses exclusions.

[Response Begins]

Yes, the measure uses exclusions.

[Response Ends]

2b.16. Describe the method of testing exclusions and what was tested.

Describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used?

[Response Begins]

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.[1]
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.[

We examined the missing frequency of each variable and calculated the facility-level performance score with and without these missing values.

References:

1. The intent of this exclusion is to allow facilities adequate time to orient and educate new patients on modality options. This is particularly important in facilities where a substantial proportion of patients have not received sufficient pre-dialysis care to allow for adequate preparation for initiation on a home modality. As many such facilities treat small rural or low-income communities, this exclusion is an important safeguard for financially vulnerable facilities treating the most socially and medically disadvantaged patients.

[Response Ends]

2b.17. Provide the statistical results from testing exclusions.

Include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores.

[Response Begins]

We present the construction of the denominator cohort for patient-months by applying the exclusion criteria. In total, 469,917 of 4,937,405 patient-months (9.5%) were excluded:

*	N of patient-months	% patient-months	N of unique patients*
Before applying any exclusions	4,937,405	*	543,115
Applying exclusion criteria	*	*	*
1. Admitted to the facility <30 days	208,790	4.2%	*
2. AKI diagnosis	98,270	2.0%	*
3. Enrolled in hospice	512	0.0%	*
4. Nursing home or LTCF resident	139,029	2.8%	*
5. Discharged from facility due to transplantation	8,474	0.2%	*
6. Discharged from facility due to death	61,064	1.2%	*
7. Discharged from facility due to discontinuation of dialysis	9,038	0.2%	*
8. Discharged from facility due to recovery of renal function	8,451	0.2%	*
Total exclusions^	469,917	9.5%	*
Final denominator, after all exclusions applied**	4,467,488	*	483,464

The table illustrates the Frequency of Exclusions

*Cell intentionally left blank.

^Note that the same patient/patient-month can appear in multiple exclusions.

**Deleted 583 records with missing facility ID.

Overall distributions and deciles of facility-level performance scores before and after applying the exclusions are shown below:

*	Mean	STD	Min	Q1	Median	Q3	Max
Without exclusions applied	13.28	23.19	0.00	0.00	0.15	18.05	100.00
With exclusions applied	14.49	25.10	0.00	0.00	0.16	19.84	100.00

The table illustrates Facility-Level Performance, Before and After Exclusions Applied

*Cell intentionally left blank.

HRR unit-level performance by DO, before and after exclusions:

*	N of HRRs	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
DO 1	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*

*	N of HRRs	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Before exclusions applied	267	15.94	10.97	0.00	10.81	14.29	17.96	94.40	7.12	10.11	11.79	13.23	15.57	17.06	19.20	24.14
After exclusions applied	267	17.26	11.90	0.00	11.58	15.54	19.43	100.00	7.78	10.81	12.71	14.40	16.78	18.35	20.64	26.20
DO 2	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Before exclusions applied	267	14.32	8.33	0.00	10.08	13.21	17.44	94.74	6.61	8.86	10.65	11.98	14.69	16.40	18.25	23.22
After exclusions applied	267	16.37	9.21	0.00	11.23	14.87	20.01	97.30	7.52	10.41	12.10	13.79	16.89	18.61	21.20	26.32

The table illustrates the Distribution and Deciles of HRR-Level Performance by Parent Organization, Before and After Exclusions Applied

*Cell intentionally left blank.

References:

1. To preserve anonymity, data are presented as coming from Dialysis Organization (DO) 1 and 2, where applicable. This nomenclature is random and is randomly scrambled throughout the measure submission documents such that DO 1 in one section might become DO 2 in another section, and vice versa.

[Response Ends]

2b.18. Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

In other words, the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion.

[Response Begins]

Our results show that 9.5% of all patients are removed from the denominator population with application of all exclusions, appreciably impacting mean performance (~1.5% change at the facility level and between 1.3 and 2% at the HRR unil-level). However, the overall frequency of the individual exclusions is low, with new patients (admitted to the facility for <30 days prior to the first day of the measurement month) and nursing home/LTCF residence resulting in the most exclusions (4.23% and 2.82%, respectively). Nevertheless, we believe the following exclusions

should be retained to minimize capture of patients for whom home dialysis prescription may not be suitable, desirable, or relevant:

- Discharge due to death (1.24%): Home dialysis is no longer relevant.
- Discharge due to transplant (0.17%): Home dialysis is no longer relevant.
- Discharge due to discontinuation of dialysis (0.18%): Home dialysis is no longer relevant.
- Discharge due to recovery of function (0.17%): Home dialysis is no longer relevant.
- Enrolled in hospice (0.01%): Limited life expectancy; financial incentivization of home dialysis prescription not appropriate.
- Receiving dialysis for AKI only (1.99%): Variable duration/prognosis; routine incentivization of home dialysis prescription not appropriate.
- Residing in nursing home/LTCF (2.82%): Complex, vulnerable patient population with frequent and multiple co-morbidities, many with limited life expectancy; financial incentivization of home dialysis prescription not appropriate.
- Admitted to facility <30 days (4.23%): Avoidance of penalizing facilities that have not had sufficient time for orientation, preparation, and training of new patients; important safeguard for financially vulnerable facilities within small rural or low-income communities treating the most socially/medically disadvantaged populations, wherein pre-dialysis care may be less common.

[Response Ends]

2b.19. Check all methods used to address risk factors.

[Response Begins]

Stratification by risk category (specify number of categories)

[Stratification by risk category (specify number of categories) Please Explain]

The measure is stratified by five risk categories: Age (0-<18 years, 18-<25, 25-<35, 35-<45, 45-<55, 55-<65, 65-<75, 75-<85, 85+), gender, race, ethnicity, dual-eligibility.

[Response Ends]

2b.20. If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.

[Response Begins]

N/A; risk adjustment is not applied.

[Response Ends]

2b.21. If an outcome or resource use measure is not risk-adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (i.e., case mix) is not needed to achieve fair comparisons across measured entities.

[Response Begins]

[Response Ends]

2b.22. Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.

[Response Begins]

Published literature

Internal data analysis

Other (specify)

[Other (specify) Please Explain]

Expert opinion from our Home Dialysis Workgroup and Steering Committee Members.

[Response Ends]

2b.23. Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.

Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10 or other statistical tests; correlation of x or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).

[Response Begins]

The conceptual model for addressing social and functional status-related risk for the KCQA Home Dialysis Rate Measure builds upon the guidance provided by NQF in its August 2021 Developing and Testing Risk Adjustment Models for Social and Functional Status-Related Risk Within Healthcare Performance Measurement Report.[1] Consistent with NQF's recommendations, we considered the following variables:

- Age;
- Gender;
- Race/ethnicity;
- Indices of social and economic vulnerability (i.e., Medicare and Medicaid dual eligibility);
- Markers of functional risk such as frailty (proxy variables were "Inability to Ambulate" and "Inability to Transfer" from Form CMS-2728); and
- Clinical variables: Blindness, dementia, incident comorbidities (CMS-2728), pre-dialysis care, cause of ESRD, BMI.

Each of the above variables has been found or is hypothesized to be associated with home dialysis utilization;[2],[3],[4] however, stratification variables for the measure were ultimately selected based on several considerations, including expert clinical input from our Home Dialysis Workgroup and Steering Committee, data availability, face validity, appropriateness (i.e., whether related to disparities in care), and empirical association with performance.

Based on input from the Steering Committee and Workgroup, and because of known disparities based on race, ethnicity, sex, and SES, these factors were included as stratification variables in our final conceptual model. Other candidate variables were not included due to issues with data availability across facilities and poor reliability of the necessary data elements.

Final stratification variables for the measure include:

- Age (0-<18 years, 18-<25, 25-<35, 35-<45, 45-<55, 55-<65, 65-<75, 75-<85, 85+)
- Gender (Male, Female)
- Race (White, Black, Other)
- Ethnicity (Hispanic, Non-Hispanic)
- Dual-eligibility status (Yes, No)

References:

1. National Quality Forum. *Developing and Testing Risk Adjustment Models for Social and Functional Status-Related Risk within Healthcare Performance Measurement: Final Technical Guidance.*
2. United States Renal Data System. 2020 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, 2020.
3. Mehrotra R et al. Racial and ethnic disparities in use of and outcomes with home dialysis in the United States. *J Am Soc Nephrol.* 2016;27:2123–2134.
4. Weiner D and Meyer K. Home dialysis in the United States: To increase utilization, address disparities. (Editorial.) *Kidney Medicine.* 2020;2(2):95-97.

[Response Ends]

2b.24. Detail the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.

[Response Begins]

We assessed for variations in overall measure performance across various sociodemographic and socioeconomic variables. Facility-level performance for the measure within risk strata is as follows:

*	N of facilities	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Overall	**5,783**	**14.58**	**25.12**	**0.00**	**0.00**	**0.16**	**20.03**	**100.00**	**0.00**	**0.00**	**0.00**	**0.00**	**9.03**	**16.77**	**24.00**	**38.13**
Age	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
0-<18	196	34.10	43.64	0.00	0.00	0.00	88.75	100.00	0.00	0.00	0.00	0.00	19.05	70.59	97.30	100.00
18-<25	2,538	22.65	37.90	0.00	0.00	0.00	40.00	100.00	0.00	0.00	0.00	0.00	0.00	10.00	63.16	100.00
25-<35	5,073	18.33	31.33	0.00	0.00	0.00	28.00	100.00	0.00	0.00	0.00	0.00	0.00	16.90	38.78	75.29
35-<45	5,573	17.13	28.65	0.00	0.00	0.00	26.67	100.00	0.00	0.00	0.00	0.00	0.00	18.61	35.29	60.00
45-<55	5,734	16.05	26.92	0.00	0.00	0.00	23.68	100.00	0.00	0.00	0.00	0.00	5.80	18.25	30.00	50.00
55-<65	5,760	14.59	25.66	0.00	0.00	0.00	20.18	100.00	0.00	0.00	0.00	0.00	5.92	15.56	24.73	42.16
65-<75	5,762	13.70	25.12	0.00	0.00	0.00	18.18	100.00	0.00	0.00	0.00	0.00	4.49	13.74	22.47	38.60
75-<85	5,723	12.41	24.98	0.00	0.00	0.00	13.81	100.00	0.00	0.00	0.00	0.00	0.00	9.57	18.66	37.42
>=85	5,061	9.20	24.31	0.00	0.00	0.00	0.00	100.00	0.00	0.00	0.00	0.00	0.00	0.00	2.63	32.08
Sex	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*

*	N of facilities	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Female	5,775	14.52	25.33	0.00	0.00	0.00	20.07	100.00	0.00	0.00	0.00	0.00	7.39	16.17	24.63	40.54
Male	5,779	14.56	25.21	0.00	0.00	0.12	20.16	100.00	0.00	0.00	0.00	0.00	7.95	16.67	24.54	38.93
Race	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
White	5,769	15.57	25.89	0.00	0.00	0.00	22.32	100.00	0.00	0.00	0.00	0.00	9.27	18.34	27.20	43.97
Black	5,465	12.90	25.79	0.00	0.00	0.00	14.29	100.00	0.00	0.00	0.00	0.00	0.31	9.84	19.26	39.02
Other	4,307	17.23	31.06	0.00	0.00	0.00	22.67	100.00	0.00	0.00	0.00	0.00	0.00	12.05	33.33	76.84
Ethnicity	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Non-Hispanic	5,779	14.65	25.21	0.00	0.00	0.17	20.42	100.00	0.00	0.00	0.00	0.00	8.82	16.79	24.57	38.63
Hispanic	4,882	14.21	28.00	0.00	0.00	0.00	15.00	100.00	0.00	0.00	0.00	0.00	0.00	8.72	21.82	52.54
Dual Eligible	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
No	5,781	15.42	25.50	0.00	0.00	0.17	22.42	100.00	0.00	0.00	0.00	0.00	9.94	19.00	26.93	41.31
Yes	5,746	11.95	24.47	0.00	0.00	0.00	12.86	100.00	0.00	0.00	0.00	0.00	1.92	9.31	17.39	32.31

The table illustrates Facility-Level Risk Stratification Analysis, Distribution and Deciles of Performance Scores, Rate as %

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At the overall HRR-level across both DOs:

*	N of HRRs	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Overall	**295**	**16.58**	**6.57**	**0.00**	**12.52**	**16.00**	**19.51**	**48.02**	**9.70**	**11.94**	**13.55**	**14.79**	**17.22**	**18.33**	**20.35**	**24.50**
Age	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
0-<18	117	35.84	39.21	0.00	0.00	16.67	70.83	100.00	0.00	0.00	0.00	0.00	46.15	66.67	85.00	97.44
18-<25	281	26.15	21.33	0.00	9.94	25.32	37.87	100.00	0.00	3.57	13.36	19.77	30.03	35.00	42.05	50.44
25-<35	294	24.13	12.06	0.00	17.43	23.84	29.41	96.77	10.27	15.49	19.46	21.07	25.71	27.98	32.05	37.14

*	N of HRRs	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
35-<45	295	22.10	10.02	0.00	15.70	21.48	26.58	67.44	11.51	15.09	17.13	19.62	23.19	25.41	27.85	33.92
45-<55	295	19.04	7.65	0.00	14.35	18.31	22.90	57.49	10.18	13.56	15.20	17.04	19.93	21.91	23.98	28.26
55-<65	295	16.43	7.79	0.00	11.71	15.25	20.00	54.63	8.70	10.53	12.80	14.20	16.93	19.03	20.65	25.31
65-<75	295	15.19	7.08	0.00	10.62	14.13	18.06	49.56	8.08	9.92	11.43	12.74	15.72	17.22	19.48	23.99
75-<85	295	13.33	7.14	0.00	8.82	12.08	16.75	46.49	6.10	7.96	9.46	10.91	13.11	15.02	18.12	22.43
>=85	295	9.88	10.89	0.00	3.99	7.67	12.27	92.31	0.00	2.84	4.68	6.18	9.33	11.10	13.74	19.60
Sex	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Female	295	16.42	6.68	0.00	12.47	15.63	19.22	43.90	9.42	11.92	13.15	14.45	16.64	18.02	20.48	25.42
Male	295	16.71	6.87	0.00	12.55	16.02	19.69	51.75	9.68	11.89	13.65	14.79	17.08	18.73	20.80	24.82
Race	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
White	295	18.65	7.55	0.00	14.18	17.95	22.38	49.78	10.42	12.90	14.94	16.61	19.45	21.44	24.03	27.69
Black	294	12.63	9.75	0.00	8.60	11.21	14.85	100.00	5.33	8.32	9.33	10.26	12.13	13.50	16.16	20.63
Other	292	20.77	15.81	0.00	11.72	18.48	26.14	100.00	2.80	9.38	13.22	16.58	21.64	25.00	28.57	34.88
Ethnicity	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Non-Hispanic	295	16.93	6.74	0.00	13.10	16.20	20.14	48.58	9.54	12.14	13.75	15.14	17.45	18.69	21.02	25.11
Hispanic	293	15.36	13.35	0.00	8.81	12.65	18.73	100.00	4.26	7.77	9.39	11.06	15.10	17.19	21.27	25.55
Dual Eligible	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
No	295	18.83	7.26	0.00	14.73	18.22	21.95	51.46	11.20	13.60	15.46	16.98	19.28	20.75	23.51	27.48
Yes	295	10.93	5.42	0.00	7.69	10.09	13.33	36.70	5.14	7.16	8.17	9.24	11.57	12.73	14.32	17.11

The table illustrates HRR-Level Risk Stratification Analysis by Parent Organization, Distribution and Deciles of Performance Scores, Rate as %

*Cell intentionally left blank.

[Response Ends]

2b.25. Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.

Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.

[Response Begins]

Stratified analyses at both the facility and HRR levels demonstrate that there is a clear trend by age (as age increases the percent on home dialysis falls), differences by race (the percent for White is higher than for Black patients, but less than for "Other" race), and that the percent on home dialysis is less among dual-eligible than non-dual-eligible patients.

While risk-adjustment might obscure these important inequities, potentially setting lower standards of quality for more sociodemographically vulnerable populations, we believe providers can and should use these stratified performance results to facilitate quality improvement efforts and focus resources on disparities reduction strategies. As such, we recommend that performance scores for the Home Dialysis Rate Measure be stratified by age, gender, race, ethnicity, and dual eligibility.

[Response Ends]

2b.26. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used). Provide the statistical results from testing the approach to control for differences in patient characteristics (i.e., case mix) below. If stratified ONLY, enter "N/A" for questions about the statistical risk model discrimination and calibration statistics.

Validation testing should be conducted in a data set that is separate from the one used to develop the model.

[Response Begins]

As above, we assessed for variations in overall measure performance across various sociodemographic and socioeconomic variables at both the facility and HRR levels.

[Response Ends]

2b.27. Provide risk model discrimination statistics.

For example, provide c-statistics or R-squared values.

[Response Begins]

N/A; measure is not risk-adjusted.

[Response Ends]

2b.28. Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).

[Response Begins]

N/A; measure is not risk-adjusted.

[Response Ends]

2b.29. Provide the risk decile plots or calibration curves used in calibrating the statistical risk model.

The preferred file format is .png, but most image formats are acceptable.

[Response Begins]

N/A; measure is not risk-adjusted.

[Response Ends]

2b.30. Provide the results of the risk stratification analysis.

[Response Begins]

As described above, we assessed for variations in overall measure performance across various sociodemographic and socioeconomic variables. At the facility-level:

*	N of facilities	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Overall	5,783	14.58	25.12	0.00	0.00	0.16	20.03	100.00	0.00	0.00	0.00	0.00	9.03	16.77	24.00	38.13
Age	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
0-<18	196	34.10	43.64	0.00	0.00	0.00	88.75	100.00	0.00	0.00	0.00	0.00	19.05	70.59	97.30	100.00
18-<25	2,538	22.65	37.90	0.00	0.00	0.00	40.00	100.00	0.00	0.00	0.00	0.00	0.00	10.00	63.16	100.00
25-<35	5,073	18.33	31.33	0.00	0.00	0.00	28.00	100.00	0.00	0.00	0.00	0.00	0.00	16.90	38.78	75.29
35-<45	5,573	17.13	28.65	0.00	0.00	0.00	26.67	100.00	0.00	0.00	0.00	0.00	0.00	18.61	35.29	60.00
45-<55	5,734	16.05	26.92	0.00	0.00	0.00	23.68	100.00	0.00	0.00	0.00	0.00	5.80	18.25	30.00	50.00
55-<65	5,760	14.59	25.66	0.00	0.00	0.00	20.18	100.00	0.00	0.00	0.00	0.00	5.92	15.56	24.73	42.16
65-<75	5,762	13.70	25.12	0.00	0.00	0.00	18.18	100.00	0.00	0.00	0.00	0.00	4.49	13.74	22.47	38.60
75-<85	5,723	12.41	24.98	0.00	0.00	0.00	13.81	100.00	0.00	0.00	0.00	0.00	0.00	9.57	18.66	37.42
>=85	5,061	9.20	24.31	0.00	0.00	0.00	0.00	100.00	0.00	0.00	0.00	0.00	0.00	0.00	2.63	32.08
Sex	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Female	5,775	14.52	25.33	0.00	0.00	0.00	20.07	100.00	0.00	0.00	0.00	0.00	7.39	16.17	24.63	40.54
Male	5,779	14.56	25.21	0.00	0.00	0.12	20.16	100.00	0.00	0.00	0.00	0.00	7.95	16.67	24.54	38.93

*	N of facilities	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Race	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
White	5,769	15.57	25.89	0.00	0.00	0.00	22.32	100.00	0.00	0.00	0.00	0.00	9.27	18.34	27.20	43.97
Black	5,465	12.90	25.79	0.00	0.00	0.00	14.29	100.00	0.00	0.00	0.00	0.00	0.31	9.84	19.26	39.02
Other	4,307	17.23	31.06	0.00	0.00	0.00	22.67	100.00	0.00	0.00	0.00	0.00	0.00	12.05	33.33	76.84
Ethnicity	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Non-Hispanic	5,779	14.65	25.21	0.00	0.00	0.17	20.42	100.00	0.00	0.00	0.00	0.00	8.82	16.79	24.57	38.63
Hispanic	4,882	14.21	28.00	0.00	0.00	0.00	15.00	100.00	0.00	0.00	0.00	0.00	0.00	8.72	21.82	52.54
Dual Eligible	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
No	5,781	15.42	25.50	0.00	0.00	0.17	22.42	100.00	0.00	0.00	0.00	0.00	9.94	19.00	26.93	41.31
Yes	5,746	11.95	24.47	0.00	0.00	0.00	12.86	100.00	0.00	0.00	0.00	0.00	1.92	9.31	17.39	32.31

The table illustrates the facility-level risk stratification analysis distribution and deciles of performance scores, rate as %

*Cell intentionally left blank.

At the overall HRR-level across both DOs:

*	N of HRRs	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Overall	**295**	**16.58**	**6.57**	**0.00**	**12.52**	**16.00**	**19.51**	**48.02**	**9.70**	**11.94**	**13.55**	**14.79**	**17.22**	**18.33**	**20.35**	**24.50**
Age	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
0-<18	117	35.84	39.21	0.00	0.00	16.67	70.83	100.00	0.00	0.00	0.00	0.00	46.15	66.67	85.00	97.44
18-<25	281	26.15	21.33	0.00	9.94	25.32	37.87	100.00	0.00	3.57	13.36	19.77	30.03	35.00	42.05	50.44
25-<35	294	24.13	12.06	0.00	17.43	23.84	29.41	96.77	10.27	15.49	19.46	21.07	25.71	27.98	32.05	37.14
35-<45	295	22.10	10.02	0.00	15.70	21.48	26.58	67.44	11.51	15.09	17.13	19.62	23.19	25.41	27.85	33.92
45-<55	295	19.04	7.65	0.00	14.35	18.31	22.90	57.49	10.18	13.56	15.20	17.04	19.93	21.91	23.98	28.26

*	N of HRRs	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
55-<65	295	16.43	7.79	0.00	11.71	15.25	20.00	54.63	8.70	10.53	12.80	14.20	16.93	19.03	20.65	25.31
65-<75	295	15.19	7.08	0.00	10.62	14.13	18.06	49.56	8.08	9.92	11.43	12.74	15.72	17.22	19.48	23.99
75-<85	295	13.33	7.14	0.00	8.82	12.08	16.75	46.49	6.10	7.96	9.46	10.91	13.11	15.02	18.12	22.43
>=85	295	9.88	10.89	0.00	3.99	7.67	12.27	92.31	0.00	2.84	4.68	6.18	9.33	11.10	13.74	19.60
Sex	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Female	295	16.42	6.68	0.00	12.47	15.63	19.22	43.90	9.42	11.92	13.15	14.45	16.64	18.02	20.48	25.42
Male	295	16.71	6.87	0.00	12.55	16.02	19.69	51.75	9.68	11.89	13.65	14.79	17.08	18.73	20.80	24.82
Race	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
White	295	18.65	7.55	0.00	14.18	17.95	22.38	49.78	10.42	12.90	14.94	16.61	19.45	21.44	24.03	27.69
Black	294	12.63	9.75	0.00	8.60	11.21	14.85	100.00	5.33	8.32	9.33	10.26	12.13	13.50	16.16	20.63
Other	292	20.77	15.81	0.00	11.72	18.48	26.14	100.00	2.80	9.38	13.22	16.58	21.64	25.00	28.57	34.88
Ethnicity	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Non-Hispanic	295	16.93	6.74	0.00	13.10	16.20	20.14	48.58	9.54	12.14	13.75	15.14	17.45	18.69	21.02	25.11
Hispanic	293	15.36	13.35	0.00	8.81	12.65	18.73	100.00	4.26	7.77	9.39	11.06	15.10	17.19	21.27	25.55
Dual Eligible	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
No	295	18.83	7.26	0.00	14.73	18.22	21.95	51.46	11.20	13.60	15.46	16.98	19.28	20.75	23.51	27.48
Yes	295	10.93	5.42	0.00	7.69	10.09	13.33	36.70	5.14	7.16	8.17	9.24	11.57	12.73	14.32	17.11

The table illustrates the HRR-level risk stratification analysis by parent organization, distribution and deciles of performance scores, rate as %

*Cell intentionally left blank.

[Response Ends]

2b.31. Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).

In other words, what do the results mean and what are the norms for the test conducted?

[Response Begins]

Again, stratified analyses demonstrate that at both the facility and HRR levels demonstrate that there is a clear trend by age (as age increases the percent on home dialysis falls), differences by race (the percent by White is higher than for Black, but less than for "Other" race), and that the percent on home dialysis is less among dual-eligible than non-dual-eligible patients.

While risk-adjustment might obscure these important inequities, potentially setting lower standards of quality for more sociodemographically vulnerable populations, we believe providers can and should use these stratified performance results to facilitate quality improvement efforts and focus resources on disparities reduction strategies. As such, we recommend that performance scores for the Home Dialysis Rate Measure be stratified by age, gender, race, ethnicity, and dual eligibility.

[Response Ends]

2b.32. Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.

Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.

[Response Begins]

N/A.

[Response Ends]

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3.01. Check all methods below that are used to generate the data elements needed to compute the measure score.

[Response Begins]

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

Other (Please describe)

[Other (Please describe) Please Explain]

The measure is intended for use by CMS in its ESRD Quality Reporting System (EQRS); all data required for the measure are already collected by facilities and submitted to CMS. The EQRS system encompasses an extensive national ESRD patient database primarily based on the Renal Management System (REMIS), EQRS facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form and CMS-2746 Death Notification Form), the Medicare Enrollment Database, Medicare claims data, transplant data from the Scientific Registry of Transplant Recipients (SRTR), and data from the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment [ASPEN]), and Dialysis Facility Compare.

[Response Ends]

3.02. Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields.

[Response Begins]

ALL data elements are in defined fields in a combination of electronic sources

[Response Ends]

3.03. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using data elements not from electronic sources.

[Response Begins]

N/A. All data elements are in defined fields in a combination of electronic sources.

[Response Ends]

3.04. Describe any efforts to develop an eCQM.

[Response Begins]

The measure has not been specified as an eCQM to date.

[Response Ends]

3.06. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

[Response Begins]

Neither missing data nor non-response were an issue with the measures during testing because the data used are routinely collected by facilities. Data regarding the number of patients each month at a facility, the number on home dialysis, and the number of consecutive months on a given modality are readily available and typically not missing. Additionally, patient information on age, sex, race, ethnicity, and dual-eligibility status is also well documented and easily retrievable.

As described in the accompanying testing data, we did learn during measure testing that dialysis facilities do not always have ready access to data on hospice enrollment and that collection of this data element varied by both parent dialysis organization and by individual facility. Similarly, capture of the nursing home/LTCF residence exclusion was somewhat variable, this time largely across parent DO. However, while during *testing* we did not have access to the complete scope and range of data available to CMS within its national ESRD patient database (e.g., data from CMS's Hospice Files or Nursing Home Minimum Data Set), we again note that the measure is intended for use by CMS in its ESRD Quality Reporting System (EQRS). If adopted by CMS for use in its ESRD accountability programs, this issue will be resolved.

Interestingly, while other data elements required to calculate the measure were readily available, we did also encounter some missingness among our stratification variables—primarily race and ethnicity. Missing values were quite small and had little effect on measure scores.

[Response Ends]

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3.07. Detail any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm),

Attach the fee schedule here, if applicable.

[Response Begins]

N/A. No outside fees or licensing are required.

[Response Ends]

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making.

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement, in addition to demonstrating performance improvement.

4a.01. Check all current uses. For each current use checked, please provide:

- **Name of program and sponsor**
- **URL**
- **Purpose**
- **Geographic area and number and percentage of accountable entities and patients included**
- **Level of measurement and setting**

[Response Begins]

Not in use

[Not in use Please Explain]

N/A. New measure not yet in use.

[Response Ends]

4a.02. Check all planned uses.

[Response Begins]

Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

Quality Improvement (internal to the specific organization)

[Response Ends]

4a.03. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

[Response Begins]

This is a new measure, not yet endorsed or in use.

[Response Ends]

4a.04. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.

[Response Begins]

KCQA plans to engage CMS and in particular the Center for Medicare and Medicaid Innovation (CMMI) to add the measure to the ETC Model and potentially the Kidney Care Choices (KCC) Models. We have had preliminary discussions this fall with CMS and plan to continue them this winter. If NQF were to endorse the measures, we believe that CMS could implement them through rulemaking for the ETC Model, which could mean the measures are proposed in 2023 and implemented for CY 2024. CMS has more flexibility with the KCC Models and could adopt the measures through guidance documents. This flexibility could mean that the measures could be incorporated into the program in CY 2024 as well. Assuming this timeline, CMMI would make the results available to the public by the end of CY 2025.

We also plan to submit the measure to the Measures Application Partnership's Measures Under Consideration list for its adoption into the ESRD programs. The measure would be submitted during the summer of 2023 (the next cycle available) for consideration and approval at the end of 2023/beginning of 2024. At that time, we may request that CMS propose the measure to be adopted in the ESRD Quality Incentive Program (QIP) as well. That would involve it being proposed in the ESRD proposed rules released in June/July 2024 and finalized in October/November 2024. Most likely, the measures would be implemented in Calendar Year 2027 or 2028. Publicly reported data would presumably be available a year after implementation.

[Response Ends]

4a.05. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail how many and which types of measured entities and/or others were included. If only a sample of measured entities were included, describe the full population and how the sample was selected.

[Response Begins]

While this is a new measure and has not yet been implemented, we tested the measure in 2022 (2021 data) within two KCQA member large dialysis organizations, each with the capacity to provide retrospective analyses from a data warehouse/repository. Performance scores were calculated at both the facility and the aggregate parent DO Hospital Referral Region (HRR) unit.[1],[2] All pertinent data from all eligible patients (i.e., adult and pediatric in-center and home hemodialysis and peritoneal dialysis, as applicable) in all facilities of the two participating LDOs during the testing period were included in the analysis. Testing encompassed 543,115 patients; 4,937,405 patient-months; 5,792 facilities; and 295 HRRs (with 267 HRRs for each of the participating DOs).

Again, we did not experience any significant issues with data availability or burden because all necessary data for the measure are already routinely collected by facilities and submitted to CMS. Accordingly, participating facilities and DOs reported no issues with data collection.

LDO's facility- and HRR-level performance scores were directly shared in follow-up webinars and other communications, as needed. Participating facilities and DOs reported that interpretation of performance scores was intuitive and results were consistent with internally tracked performance.

[1] To account for home dialysis–only facilities within a Hospital Referral Region (HRR), particularly if a parent company sends its home dialysis patients to such a provider, the measure allows for aggregation of facilities

owned by the same company within a given HRR. Specifically, a subsidiary facility's Home Dialysis Rate is aggregated to the facility's aggregation group, which includes all dialysis facilities owned in whole or in part by the same legal entity ("Parent Organization") located in the HRR in which the facility is located.

[2] Data for measure testing were collected at the facility level, then aggregated to the parent DO HRR level (where applicable). Throughout the submission materials, testing results are presented at both the facility-level and the HRR-level; this approach allows for NQF assessment of how "independent" facilities that are not subsidiaries of any parent company might perform. Additionally, HRR data are presented at the DO-level only where important/necessary to illustrate differences across the DOs; otherwise, the "overall" HRR-level data across both DOs are presented to preserve company anonymity.

[Response Ends]

4a.06. Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

[Response Begins]

Again, this is a new measure and has not yet been implemented. As above, participating LDO's facility- and HRR-level performance scores from measure testing were directly shared in follow-up webinars and other communications, as needed. Participating facilities and DOs reported that interpretation of performance scores was intuitive, and results were consistent with internally tracked performance. There were no instances where additional educational/explanatory efforts were required.

[Response Ends]

4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

[Response Begins]

Again, this is a new measure and has not yet been implemented. As above, participating LDO's facility- and HRR-level performance scores from measure testing were directly shared in follow-up webinars and other communications, as needed. Feedback on the measures was obtained at this time as well. Participating facilities and DOs reported they did not experience any significant issues with data availability or measure burden because all necessary data for the measure are already routinely collected by facilities and submitted to CMS. Accordingly, participating facilities and DOs reported no issues with data collection or measure implementation.

[Response Ends]

4a.08. Summarize the feedback obtained from those being measured.

[Response Begins]

As above, participating LDOs did not experience significant issues with data availability, data collection, or measurement burden because all necessary data for the measure are already routinely collected by facilities and submitted to CMS. Likewise, participating facilities and DOs reported that interpretation of performance scores was intuitive, and results were consistent with internally tracked performance. There were no recommendations for any measure revisions.

[Response Ends]

4a.09. Summarize the feedback obtained from other users.

[Response Begins]

N/A. This is a new measure and has not yet been implemented; we have received no feedback beyond that obtained during measure testing.

[Response Ends]

4a.10. Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

[Response Begins]

N/A. The measure has been submitted to NQF as tested, without modification or revision.

[Response Ends]

4b.01. You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included). If no improvement was demonstrated, provide an explanation. If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

[Response Begins]

As noted in the Gap in Care/Disparities section, federal policy-makers and the entire kidney care community have identified the rate of home dialysis adopted in the United States as being far below that of other developed nations.[1] The adoption of the KCQA Home Dialysis Measures in the ETC Model would support the stated goal of the model and the interest of the kidney care community to increase the utilization of home dialysis among individuals with ESKD who require dialysis. The model seeks to incentivize facilities and managing clinicians to encourage them to "ensure that ESRD beneficiaries have access to and receive education about their kidney disease treatment options."[2] Providers that do not meet annually escalating benchmarks will see their payments cut. The model relies on the calculation of a dialysis rate to determine the penalties. As noted in questions 5.03 and 5.06, the KCQA Home Dialysis Measures would be superior to the current rate calculation CMS set forth in regulation because: (1) its validity and reliability has been recognized by the NQF's Scientific Methods Panel; (2) its specifications provide greater transparency and address the appropriate exclusion of certain types of patients that should not be included in the metric; and (3) it is intended to be paired with a guardrail measure (the KCQA Home Dialysis Retention Measure) that will discourage providers from placing patients on home dialysis when the modality is not medically appropriate for them, to counter the overwhelming financial incentives built into the ETC Model. These measures together will provide accurate, meaningful, transparent information to further the goals of increasing the adoption of home dialysis modalities.

A similar rationale applies to the adoption of the measure in the KCC Models, as well as the ESRD QIP in the traditional Medicare program.

[1]Centers for Medicare & Medicaid Services. "ESRD Treatment Choices (ETC) Model." https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model. Last Updated Oct. 25, 2022.

[2] *Ibid.*

[Response Ends]

4b.02. Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

[Response Begins]

N/A. New measure not yet in use.

[Response Ends]

4b.03. Explain any unexpected benefits realized from implementation of this measure.

[Response Begins]

N/A. New measure not yet in use.

[Response Ends]

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

If you are updating a maintenance measure submission for the first time in MIMS, please note that the previous related and competing data appearing in question 5.03 may need to be entered in to 5.01 and 5.02, if the measures are NQF endorsed. Please review and update questions 5.01, 5.02, and 5.03 accordingly.

5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.)

[Response Begins]

[Response Ends]

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.)

[Response Begins]

[Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

[Response Begins]

While not formally specified, tested, submitted for NQF endorsement, or released for public review and comment, CMS currently includes a metric addressing HRR-level home dialysis utilization within the ETC Model, defined as follows:

Home Dialysis Rate = ([Home Dialysis + ½ In-Center Self-Care + ½ Nocturnal In-Center Dialysis] patient-years)/Total dialysis patient-years

[Response Ends]

5.04. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

[Response Begins]

Yes

[Response Ends]

5.05. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

[Response Begins]

N/A; there is no NQF-endorsed measure addressing the same focus or target population.

[Response Ends]

5.06. Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.

[Response Begins]

The KCQA Home Dialysis Rate Measure is superior to the current metric within the ETC Model for the following reasons:

- The ETC metric does not provide a clear assessment of home dialysis utilization; rather, the metric includes in-center self-care and in-center nocturnal dialysis patient-years in the numerator, each scored at ½ the value of a home dialysis patient-year. As such, home dialysis performance is obfuscated in reported results, minimizing the metric's utility as an effective tool to assess or incentivize home dialysis utilization or to facilitate performance improvement.
- The ETC metric excludes both pediatric and non-Medicare patients; conversely, the KCQA measure is inclusive of all clinically appropriate dialysis patients, as our Workgroup and Steering Committee did not believe there was a supportable rationale to exclude any populations for these analyses.
- The KCQA measure more precisely identifies clinically appropriate patients for inclusion in the denominator population than the ETC metric by excluding 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. Such patients are no longer clinically appropriate for inclusion in the denominator and capture of these patient-months will inappropriately adversely impact scores.
- Finally, we note that while the KCQA Home Dialysis Rate Measure can stand alone, we recommend it be paired with the accompanying KCQA Home Dialysis Retention Measure for optimal results. At current, approximately one-quarter of all patients who initiate home dialysis will return to in-center hemodialysis within two years.[1] While the ETC initiative has the potential to dramatically change nephrology and dialysis care in the United States, there is concern among stakeholders that this unilateral focus on home dialysis growth in a healthcare system not adequately prepared for such an influx may lead to suboptimal outcomes and have unintended, prolonged negative effects on home dialysis. Incentivizing a rapid rise in the use of home dialysis in the absence of safeguards and a sufficiently robust infrastructure to support such growth will certainly lead to increased technique failure rates. It may also subject many patients to a treatment modality for which they have not received adequate education or training, and may even inadvertently result in infringement on patient choice. To address such concerns, KCQA's "Home Dialysis Measure Set" has been developed and designed 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 rate measure were implemented alone, minimizing the potential adverse consequences of unchecked home dialysis growth. 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 current ETC home dialysis metric does not provide any such counterbalancing measure or incentives, and may thus place patients at increased risk of treatment failures, which has been a central concern raised by patients and patient advocates regarding the use of a rate metric alone in the ETC model.
- To our knowledge, the current ETC home dialysis measure has not been tested to determine reliability or validity, and has not been released for stakeholder review and comment. Similarly, it has not been subjected to the rigorous review of the NQF endorsement process. Given that the NQF Scientific Methods Panel passed the KCQA measure during its review of reliability and validity, the KCQA measure is superior to the untested, unevaluated ETC measure.

[1] 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.

[Response Ends]

Appendix

Supplemental materials may be provided in an appendix.:

Available in attached file

Attachment: 3722_KCQA Expert Panel for Face Validity Assessment-508.pdf

Contact Information

Measure Steward (Intellectual Property Owner): Kidney Care Quality Alliance

Measure Steward Point of Contact: McGonigal, Lisa, lmcgon@msn.com

Lester, Kathy, klester@lesterhealthlaw.com

Measure Developer if different from Measure Steward: Kidney Care Quality Alliance

Measure Developer Point(s) of Contact: McGonigal, Lisa, lmcgon@msn.com

Lester, Kathy, klester@lesterhealthlaw.com

Additional Information

1. Provide any supplemental materials, if needed, as an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be collated one file with a table of contents or bookmarks. If material pertains to a specific criterion, that should be indicated.

[Response Begins]

Available in attached file

[Response Ends]

Attachment: 3722_KCQA Expert Panel for Face Validity Assessment-508.pdf

2. List the workgroup/panel members' names and organizations.

Describe the members' role in measure development.

[Response Begins]

The KCQA Home Dialysis Technical Workgroup was convened in summer 2021 to conceptualize and develop the Home Dialysis Measures. The Workgroup was made up of one ESRD patient that had experience with both in-center and home dialysis, five clinicians that treat in-center and home ESRD dialysis patients (adult and pediatric nephrologists and nephrology nurses), one dialysis facility administrator/manager, and one epidemiologist with over 15 years of research focusing primarily on home dialysis:

1. Donna Painter, MS, RN, CNN (American Nephrology Nurses Association)
2. Rajnish Mehrotra, MD, MS (American Society of Nephrology)
3. Avram Z. Traum, MD (American Society of Pediatric Nephrology)
4. Emiliya Kechker (B. Braun Medical, Inc.)
5. Vanessa Evans (Dialysis Patient Citizens, Inc.)
6. Bryan Fore (Fresenius Medical Care North America)
7. Rebecca Schmidt, DO, FACP, FASN (Renal Physicians Association)
8. Eric Weinhandl PhD, MS (University of Minnesota)

The Home Dialysis project was also guided by KCQA's broad-based 15-member Steering Committee comprised of patients/advocates, physicians, nurses, and researchers, and manufacturers from organizations across the full range of KCP's membership:

1. Todd Eric Minga, MD (Akebia Therapeutics, Inc.)
2. Gail Wick, MHSA, BSN, RN, CNN (American Kidney Fund, Inc.)
3. Donna Bednarski, MSN, RN, ANP-BC, CNN, CNP (American Nephrology Nurses Association)
4. Daniel E. Weiner, MD, MS (American Society of Nephrology)
5. J. Ganesh Bhat, MD (Atlantic Dialysis Management Services, LLC)
6. George R. Aronoff, MD, MS, FACP, FASN, Co-Chair (DaVita, Inc.)
7. James "Mike" Guffey (Dialysis Patient Citizens, Inc.)
8. Lorien Dalrymple, MD, MPH (Fresenius Medical Care)
9. Robert S. Bomstad, MS, BS, RN (Renal Healthcare Association)
10. Keith A. Bellovich, DO, Co-Chair (Renal Physicians Association)
11. Lori Hartwell (Renal Support Network)
12. Jeffrey Silberzweig, MD (Rogosin Institute)

13. Brigitte Schiller, MD (Satellite Healthcare)
14. Mary Dittrich, MD, FASN (U.S. Renal Care, Inc.)
15. Amy Barton, PharmD, MHI (Vifor Pharma)

The Home Dialysis Measures were also reviewed and approved as specified by KCQA's full membership body, consisting of Organizational Lead Representatives from all participating members:

1. Todd Berner (Akebia Therapeutics, Inc.)
2. Gail Wick (American Kidney Fund, Inc.)
3. Glenda Payne (American Nephrology Nurses' Association)
4. Keisha Greene (American Renal Associates, Inc.)
5. Daniel E. Weiner (American Society of Nephrology)
6. Michael Somers (American Society of Pediatric Nephrology)
7. Tricia Brooks (Ardelyx)
8. Henry Cermisi (AstraZeneca)
9. J. Ganesh Bhat (Atlantic Dialysis Management Services, LLC)
10. Sam Amory (B. Braun Medical, Inc.)
11. Scott Terillion (Cara Therapeutics)
12. Sharon Thomas (Centers for Dialysis Care)
13. Anne Boardman (CorMedix, Inc.)
14. Steve Brunelli (DaVita, Inc.)
15. Alice Hellebrand (DialyzeDirect)
16. James Michael Guffey (Dialysis Patient Citizens)
17. Stacey Fahrner (Fresenius Medical Care North America)
18. Michael Anger (Fresenius Renal Therapies Group)
19. William Poirie (Greenfield Health Systems)
20. Cherilyn Cepriano (Kidney Care Council)
21. Nieltje Gedney (Home Dialyzers United)
22. Wade Delk (North American Transplant Coordinators Organization)
23. Kathy Houle (Nephrology Nursing Certification Commission)
24. Heidi Waters (Otsuka America Pharmaceutical, Inc.)
25. Bridget Pfaff (Renal Healthcare Association)
26. Yaakov Liss (Renal Physicians Association)
27. Lori Hartwell (Renal Support Network)
28. Helen Currier (Rockwell Medical)
29. Jeffrey Silberzweig (Rogosin Institute)
30. Patrice Smith (Satellite Healthcare)
31. Thomas Weinberg (U.S. Renal Care)
32. James Ingram (Vertex Pharmaceuticals)
33. Amy Barton (Vifor Pharma Ltd.)

Finally, we convened a panel of patients and experts in the field of ESRD and dialysis care and uninvolved in the KCQA measure development process were identified from Kidney Care Partner (KCP) member organizations and

were invited to participate in a formal face validity assessment of the KCQA Home Dialysis Measures. The resulting panel of 35 consisted of 12 renal patients, 2 patient advocacy groups, and 19 nephrologists and 2 executive leaders from 16 provider organizations and universities:

1. LaVarne Burton, American Kidney Fund, President
2. Steven Weiss, Atlantic Dialysis Management Services, Vice President of Quality
3. Shaun Conlon, MD, Atlanta Nephrology Associates, Nephrologist
4. Samaya Anumudu, MD, Baylor College of Medicine, Nephrologist
5. Kevin Erickson, MD, MS, Baylor College of Medicine, Nephrologist
6. Yash Chivate, MD, Cooper University Health Care, Nephrologist
7. Lawrence S. Weisberg, MD, Cooper University Health Care, Nephrologist
8. Ron Zanger, MD, Cooper University Hospital, Nephrologist
9. Melissa Echols, *Dallas Nephrology Associates, Nephrologist*
10. Allen Nissenson, MD, David Geffen School of Medicine at UCLA, Nephrologist
11. Jeff Giullian, MD, DaVita, Nephrologist
12. Adam Weinstein, MD, DaVita, Nephrologist
13. Robert Kossman, MD, Fresenius Medical Care, CMO
14. Nupur Gupta, MD, Indiana University, Nephrologist
15. Scott Bieber, DO, Kootenai Health, Nephrologist
16. Bharat Sachdeva, MD, Louisiana State University, Nephrologist
17. Wendy Rodgers, M.Ed, MPH, Lupus Foundation of America, Director of Care and Support Services
18. Joanna Y Galeas, Renal Support Network, Renal Patient
19. Lori Hartwell, Renal Support Network, Renal Patient
20. Shane Moore, Renal Support Network, Renal Patient
21. Wesley Stewart, Renal Support Network, Renal Patient
22. Cher Thomas, Renal Support Network, Renal Patient
23. Susan Vogel, Renal Support Network, Renal Patient
24. Lubna Akbany, Unaffiliated Renal Patient
25. Lori Ann Battelli, Unaffiliated Renal Patient
26. Mike Gothard, Unaffiliated Renal Patient
27. Isela King, Unaffiliated Renal Patient
28. Suzette Maffi, Unaffiliated Renal Patient
29. Cheri Rodriguez Jones, Unaffiliated Renal Patient
30. Pranav S. Garimella, MBBS, MPH, University of California San Diego, Nephrologist
31. Paul Palevsky, MD, University of Pittsburgh, Nephrologist
32. Peggy Bushey, University of Vermont Medical Center, Dialysis Manager
33. Joseph Flynn, MD, University of Washington Seattle Children's Hospital, Nephrologist
34. Sri Lekha Tummalapalli, MD, MBA, MS, Weill Cornell Medicine, Nephrologist
35. Edward Gould, MD, Vanderbilt Health, Nephrologist

[Response Ends]

3. Indicate the year the measure was first released.

[Response Begins]

2021

[Response Ends]

4. Indicate the month and year of the most recent revision.

[Response Begins]

September 2022

[Response Ends]

5. Indicate the frequency of review, or an update schedule, for this measure.

[Response Begins]

Reviews will take place annually in August.

[Response Ends]

6. Indicate the next scheduled update or review of this measure.

[Response Begins]

August 2023

[Response Ends]

7. Provide a copyright statement, if applicable. Otherwise, indicate "N/A".

[Response Begins]

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[Response Ends]

8. State any disclaimers, if applicable. Otherwise, indicate "N/A".

[Response Begins]

Dialysis facility performance measures (Measures) and related data specifications, developed by the Kidney Care Quality Alliance (KCQA), primarily funded by Kidney Care Partners, are intended to facilitate quality improvement activities by dialysis providers.

These Measures are intended to assist dialysis facilities and organization in enhancing quality of care. Measures are designed for use by any dialysis facility or organization. These performance Measures are not clinical guidelines and do not establish a standard of medical care. KCQA has not tested its Measures for all potential applications. KCQA encourages the evaluation of its Measures.

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[Response Ends]

9. Provide any additional information or comments, if applicable. Otherwise, indicate “N/A”.

[Response Begins]

N/A.

[Response Ends]