NATIONAL QUALITY FORUM
Driving measurable health improvements together

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through National Quality Forum's (NQF) Consensus Development Process (CDP). The information submitted by the measure developers/stewards is included after the *Brief Measure Information* and *Preliminary Analysis* sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Brief Measure Information

NQF #: 3725

Corresponding Measures:

Measure Title: Home Dialysis Retention

Measure Steward: Kidney Care Quality Alliance

sp.02. Brief Description of Measure: Percent of all new home dialysis patients in the measurement year for whom >=90 consecutive days of home dialysis was achieved.

1b.01. Developer Rationale:

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

Accordingly, increasing home dialysis is a major objective of the ESRD Treatment Choices (ETC) Payment Model launched CMS in January 2021, and home dialysis utilization has been identified as one of the performance metrics that will be used in the 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.

KCQA's Home Dialysis Measure 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 basic premise of the measure set 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:

Home Dialysis Retention Measure Logic

Specifically, adoption of the Home Dialysis Retention Measure will incentivize the facility to implement process interventions (e.g., effective modality education, appropriate patient preparation/training/support) to improve home dialysis retention among patients who have selected and commenced a home modality.

As noted in our accompanying KCQA Home Dialysis Rate Measure (NQF 3722) submission, while the Rate Measure can stand alone, we recommend it be paired with the 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. 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. 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.

sp.12. Numerator Statement: Patients from the denominator who achieved >=90 consecutive days of home dialysis in the measurement year.

sp.14. Denominator Statement: The total number of eligible new home dialysis patients attributed to the dialysis facility during the measurement year.

sp.16. Denominator Exclusions:

Denominator patients who are discharged from the facility for any of the following events occurring <90 days after meeting the 30-day eligibility criterion [1] are excluded:[2]

- Transplant;
- Death;
- Discontinuation of dialysis;
- Recovery of function;
- Admission to hospice; and/or

Admission to nursing home or other LTCF.

Measure Type Outcome: Intermediate Clinical Outcome

sp.28. Data Source:

Electronic Health Data

Electronic Health Records

sp.07. Level of Analysis:

Facility

Other

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

#3725 - Home Dialysis Retention

#3722 - Home Dialysis Rate

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

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

Preliminary Analysis: New Measure

Criteria 1: Importance to Measure and Report

1a. Evidence

1a. Evidence. The evidence requirements for a ***structure, process, or intermediate outcome*** measure are that it is based on a systematic review (SR) and grading of the body of empirical evidence in which the specific focus of the evidence matches what is being measured. For measures derived from a patient report, the evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following description for this measure:

- This is a new intermediate clinical outcome measure at the facility level that measures the percentage of all new home dialysis patients in the measurement year for whom greater than or equal to 90 consecutive days or more of home dialysis was achieved.
- The developer provides a logic model that depicts the relationship between the individual measure components, process interventions, and the desired health outcomes which include lowering patient mortality, hospitalization, and cardiovascular risks, while improving patients' quality of life, and reducing the cost of care. Specifically, adoption of the home dialysis measure will incentivize the facility to implement process interventions such as effective modality education, and appropriate patient preparation, training, and support to improve home dialysis retention among patients who have selected and commenced a home modality.

The developer provides the following evidence for this measure:

- SR of the evidence specific to this measure? ☐ Yes ☒ No
- Quality, Quantity, and Consistency of evidence provided? ☐ Yes ☒ No
- Evidence graded? ☐ Yes ☒ No

Summary:

- The developer noted that there are no relevant clinical practice guidelines, United States Preventive Services Task Force (USPSTF) recommendations, systematic reviews, or formal randomized controlled studies addressing home dialysis modalities uptake or retention.
- The developer cited observational studies and 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 end-stage renal disease (ESRD) patient that had experience with both in-center and home dialysis, five clinicians that treat in-center and home ESRD dialysis patients, one dialysis facility administrator, and one epidemiologist with over 15 years of research focusing primarily on home dialysis.
    - The developer states that the workgroup unanimously approved the measure specifications and that the measure was unanimously supported by KCQA's broad-based 15-member Steering Committee and full membership, comprised of patients/advocates, physicians, nurses, researchers, and manufacturers.
- The developer provides evidence from observational studies that states:
    - Home dialysis is underutilized with home dialysis rates remaining low in the United States compared with many other countries, hovering around 15 percent.
    - Home dialysis is associated with equivalent clinical outcomes, such as hospitalization rates and mortality, and superior patient-reported outcomes, such as physical and mental quality of life.
    - Patients support increased home dialysis use.
        - Approximately 30 percent of chronic dialysis patients report that they do not believe they have made a fully informed choice regarding modality, with this finding being most prevalent among in-center HD patients.
        - Decision-making efficacy and satisfaction of modality selection has also been reported as greater among peritoneal dialysis (PD) vs in-center HD patients.
    - Keeping patients on home dialysis long term remains a challenge.
        - According to the United States Renal Data System (USRDS), 25 percent of patients who initiated home hemodialysis in 2017 to 2018 had converted to in-center hemodialysis after 2 years, with the corresponding conversion with PD being 24 percent.
        - The attrition rate is highest during the first 3 to 4 months of treatment for both PD and HD patients.
    - Increasing home dialysis utilization is now a major CMS objective.
        - In January 2021, the ESRD Treatment Choices (ETC) Payment Model was launched to encourage greater use of home dialysis for Medicare beneficiaries to reduce costs while preserving or enhancing the quality of ESRD care.
        - Home dialysis utilization is now a metric that dialysis facilities and organizations within the ETC program will be evaluated on.

Exception to evidence

- Measure may be eligible to pass with an exception if the Standing Committee agrees that empirical data was not provided for the measure or part of the measure, no alternative measures exist or could exist, the measure is supported by a systematic assessment of expert opinion and that it would be acceptable or beneficial to hold providers accountable without empirical evidence.

Questions for the Standing Committee:

- *What is the relationship between this measure and patient outcomes?*
- *How strong is the evidence for this relationship?*
- *Is the evidence directly applicable to the process of care being measured?*
- *Are there, or could there be, performance measures of a related health outcome OR evidence-based intermediate clinical outcomes and/or intervention/treatment?*
- *Is there evidence of a systematic assessment of expert opinion beyond those involved in developing the measure?*
- *Does the Standing Committee agree that it is acceptable (or beneficial) to hold providers accountable without empirical evidence?*

Guidance From the Evidence Algorithm

Not an outcome measure (Box 1) -> Intermediate clinical outcome measure not based on a systematic review (Box 3) -> Empirical evidence is submitted without systematic review and grading of the evidence (Box 7) -> Empirical evidence summarized (Box 8) -> Moderate

The highest possible rating is moderate.

Preliminary rating for evidence: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

1b. Gap in Care/Opportunity for Improvement and Disparities

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- The developer calculated 2021 performance scores during measure testing at the individual facility level and reports that:
    - Testing encompassed 30,549 eligible new home dialysis patients regardless of patient age, vintage, or payer.
    - Only 2,812 of the 5,781 facilities across the two participating DOs had new home dialysis patients to contribute to the denominator and were included in the analysis.
    - The developer found a mean performance of 74.7 percent, a standard deviation of 30.5 percent and an interquartile range of 31.2 percent.

Disparities

- The developer reports that a stratified analysis of performance led to notable variations in performance across demographic groups, with trends being identified by age, race, ethnicity, and insurance status.
    - The developer notes that regarding age, patients under 18 were achieving 90 or more days of home dialysis more consistently than older age groups.
    - The developer reports that concerning race, there was a higher performance among "other" races (81.8 percent) than in black (78.9 percent) or white (77.3 percent) patients.

- The developer states that regarding ethnicity, Hispanics (82.8 percent) performed more than 7 percent higher than non-Hispanics (75.2 percent).
- The developer notes that dual eligible (79.1 percent) patients were performing slightly better than non-dual eligible (76.5 percent) patients.

Questions for the Standing Committee:

- *Is there a gap in care that warrants a national performance measure?*

Preliminary rating for opportunity for improvement: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Criteria 2: Scientific Acceptability of Measure Properties

Complex measure evaluated by the Scientific Methods Panel (SMP)? ☒ **Yes** ☐ **No**

Evaluators: Christie Teigland, Alex Sox-Harris, Jack Needleman, Sean O'Brien, Matt Austin, Larry Glance, Marybeth Farquhar, Sherrie Kaplan, Terri Warholak, Sam Simon, Joe Hyder, Susan White

- The SMP passed on Reliability with a score of: H-0; M-5; L-2; I-1.
- The SMP passed on Validity with a score of: H-1; M-7; L-2; I-1.

2a. Reliability: Specifications and Testing

2a1. Specifications require the measure, as specified, to produce consistent (i.e., reliable) and credible (i.e., valid) results about the quality of care when implemented.

2a2. Reliability testing demonstrates whether the measure data elements are repeatable and producing the same results a high proportion of the time when assessed in the same population in the same time period, and/or whether the measure score is precise enough to distinguish differences in performance across providers.

Specifications:

- This measure was previously submitted to the SMP under NQF #3697 as a clinical intermediate outcome measure. The developer has resubmitted it as a clinical intermediate outcome measure under NQF #3725.
- To account for previous feedback from the SMP, the developer kept the level of analysis at the facility but provided an explanation as to why HRR-level analysis is not required (see below under "Reliability Testing").
- Measure specifications are clear and precise.

Reliability Testing:

- Reliability testing was conducted at the accountable-entity level:
  - Reliability testing was conducted at the facility level using signal-to-noise analysis: the beta-binomial model. The developer states that HRR-level aggregation is not necessary for this measure because it only includes incident patients and does not need to account for facilities that do not offer home dialysis.
  - Mean reliability at the facility level (N=2,812) using one year of data was 0.604 (median= 0.547). The median facility had seven patients.

- The developer noted that while the reliability statistics using one year of data meet NQF's criteria, they also calculated reliability by duplicating their data and treating it as a two-year rolling measure, given the small numbers of new home dialysis patients. The mean reliability increased to 0.846 (a median of 0.905) with the second year of data.
- The developers noted that to confirm that the double use of the 2021 data provides a valid analysis, they performed an additional analysis by randomly generating new yearly data for each facility and combined that with the 2021 data, resulting in a similar increase in reliability (0.871 with a median of 0.931). The developers argue that this additional analysis helps to alleviate concerns of autocorrelation.

SMP Summary:

- Two SMP members noted that the Standing Committee should discuss what happens if a dialysis patient enters the denominator after October 1 and cannot meet the 90-day threshold and whether the choice of only including patients already retained for 30 days is best.
- The measure is specified for one year, but the measure developer advised that if the measure is implemented, reliability would be improved with a two-year construct. One SMP member noted that, given the developers response to NQF clarification on the two-year rolling requirement, the measure should not be implemented as a one-year measure. Several other members noted that low volume units do not have adequate reliability for the one-year measure as well. Lastly, one SMP member noted that the calculations used for reliability may be overestimating the true reliability due to the small facility-specific denominators and a lack of precision in the denominator estimates.
    - The developer noted that this measure only captures new home dialysis patients in a measurement year, and that only facilities offering or providing home dialysis in the measure year are captured in the measure denominator. As a result, the facility size could be an issue when calculating reliability. However, the developer hypothesizes that a rolling-year measure construct might increase measure reliability. This hypothesis was tested by the developer by randomly generating new "yearly" data for each facility with the assumption that, in the new year, each facility had the same facility size (number of patients had home dialysis) and the same performance on retention of home dialysis for at least 90 days. The developer combined the 2021 data with the newly simulated yearly data and performed the analysis.
    - The developer agreed with the second issue raised that the calculations used for reliability may be overestimating the true reliability due to small facility-specific denominators and a lack of precision in the denominator estimates. The developer responded to this issue by recalculating reliabilities for both single year and double year data using the new reliability formula when sample size is small. The developer noted that the new results confirmed the reviewer's concern that the reliability may be overestimated for small facilities using the method in this submission. The new results are as follows:
        - For 2021 single year data, the Q1, median, and Q3 reliabilities (vs in submission) are 0.1218 (vs 0.2740), 0.2444 (vs 0.5473), and 0.3753 (vs 1.000).
        - For combined 2021 and simulated data, the Q1, median, and Q3 reliabilities (vs in submission) are 0.5840 (vs 0.7862), 0.7661 (vs 0.9313), and 0.8588 (vs 1.000).

Questions for the Standing Committee regarding reliability:

- *Do you have any concerns that the measure cannot be consistently implemented (i.e., are the measure specifications adequate)?*

- *The SMP is satisfied with the reliability testing for the measure. Does the Standing Committee think there is a need to discuss and/or vote on reliability?*

Preliminary rating for reliability: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

2b. Validity: Validity Testing; Exclusions; Risk Adjustment; Meaningful Differences; Comparability; Missing Data

2b2. Validity testing should demonstrate that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, identifying differences in quality.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Validity Testing

- Validity testing was conducted at the accountable-entity level:
  - Validity testing was conducted using face validity with a panel of nine members (five healthcare providers, two dialysis facilities, and three manufacturer groups).
  - Seven of the nine members agreed that the measure score or highly likely provides an accurate reflection of quality and that the measure would effectively distinguish real differences in performance between providers.
  - Eight of the nine members agreed that the measure scores for the paired set (NQF #3722 and NQF #3725) will provide an accurate reflection of quality and that the paired set will effectively distinguish real differences in performance between providers.
  - A dissenting member noted concerns about the minimal patient exclusion criteria and that this would reflect the provider's patient population and not their performance.

Exclusions

- The following exclusions are applied to the denominator: patient months with hospice (0.0 percent); patient months in a nursing home or other LTCF (1.0 percent); and patient discharge secondary to transplant (0.4 percent), death (1.8 percent), discontinuation of dialysis (0.5 percent), and/or recovery of renal function in the month (0.1 percent). After accounting for overlap in exclusions, 3.1 percent unique patient months were excluded from the denominator. The mean facility-level performance before exclusions was 72.4 percent, and with them applied, it was 74.7 percent. The developer notes that these exclusions are clinically warranted to avoid creating a disincentive for home dialysis trials by penalizing providers for unanticipated events beyond their control that prevent a patient from achieving the 90-day numerator criterion.

Risk Adjustment

- The developer risk-stratified the measure by age, gender, race/ethnicity, and dual-eligible status. They also explored markers of functional risk and clinical variables for stratification, but they were not included due to data availability.
- Stratified analyses of performance demonstrate that a clear trend by age (with patients under the age of 18 achieving 90 or more days of home dialysis more consistently than older age groups), differences by race (with higher performance in "Other" races than in Black or White patients) and ethnicity (with Hispanics performing more than 7 percent higher than non-Hispanics), and by insurance status (with dual-eligible patients performing slightly better than non–dual-eligible patients).

Meaningful Differences

- The mean performance was 74.7 percent and the 25th percentile. The median and 75th percentile performance scores are 69 percent, 83.3 percent, and 100 percent.
- To demonstrate the statistical significance of the spread, the developer used the 2021 data and the randomly generated data and analyzed 1,699 facilities with a non-zero performance score. The overall weighted mean performance score was 80.4 percent with the facility size as the weight. The developer noted this as the national norm. Sixty percent of facilities with a score between 6.25 percent and 52.87 percent (below the 10th decile) had 95 percent CIs (Confidence Interval) below the norm. Facilities with a score greater than 92.86–98.53 percent (90th decile and above) all had 95 percent CIs above the norm. The developers noted that measuring performance scores can identify facilities with good performance, but the identification of facilities with poor performance was more variable due to the small facility size.

Missing Data

- The developer notes that while they believe their observed percentage of patient-months excluded secondary to hospice enrollment is not accurate, they believe those same patients are captured in other exclusions. The developer also believes their observed percentage of patient-months excluded due to nursing/LTCF residence is an underestimate. However, they note that if they were to use the highest exclusion rate reported, there is only a difference of 0.4 percent in the overall facility-level score.
- When patient months were excluded from the denominator due to missing values in the stratification variables (e.g., age, sex, race, ethnicity, and dual-eligibility status), the mean facility-level performance was 74.7 percent before exclusions and 74.8 percent after excluding missing values.

Comparability

- The measure only uses one set of specifications for this measure.

SMP Summary:

- The SMP had no concerns regarding the validity testing.

Questions for the Standing Committee regarding validity:

- *Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk adjustment approach, etc.)?*
- *The SMP is satisfied with the validity analyses for the measure. Does the Standing Committee think there is a need to discuss and/or vote on validity?*

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Criterion 3. Feasibility

3. Feasibility is the 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.

- The developer states that the data elements are generated or collected by and used by healthcare personnel during the provision of care.

- The developer states the measure relies on data elements defined in a combination of electronic sources.
- The developer states that the measure is intended for use by CMS in its ESRD Quality Reporting System (EQRS) and that all data required for the measure are already collected by facilities and submitted to CMS.

Questions for the Standing Committee:

- *Are the required data elements routinely generated and used during care delivery?*
- *Are the required data elements available in electronic form (e.g., EHR or other electronic sources)?*
- *Is the data collection strategy ready to be put into operational use?*

Preliminary rating for feasibility: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Criterion 4: Use and Usability

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluates the extent to which audiences (e.g., consumers, purchasers, providers, and policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If they are not in use at the time of initial endorsement, then a credible plan for implementation within the specified time frames is provided.

Current uses of the measure

Publicly reported?	☐	Yes	☒	No		
Current use in an accountability program?	☐	Yes	☒	No	☐	UNCLEAR
Planned use in an accountability program?	☒	Yes	☐	No	☐	NA

Accountability program details

- This is a new measure and is therefore not currently in use.
- The developer plans to engage the Center for Medicare and Medicaid Innovation (CMMI) to add the measure to the ETC model and possibly to the Kidney Care Choices (KCC) Models for implementation in 2024. As a result, results would become available to the public by the end of 2025.
- The developer also plans to submit this measure to the Measures Under Consideration (MUC) list for adoption into the ESRD programs. In addition to doing so, the developer states they may request for CMS to propose the measure to be adopted in the ESDR proposed rules. As a result, measures would be implemented in 2027 or 2028, with public reported data becoming available a year after implementation.

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: (1) Those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; (2) Those being measured, and other users have been given an opportunity to provide feedback on the measure performance or implementation; and (3) This feedback has been considered when changes are incorporated into the measure.

Feedback on the measure provided by those being measured or others

- This is a new measure; therefore, no feedback has been obtained by those being measured or measure users. However, the measure was tested in 2022 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 the facility level and testing encompassed 30,549 eligible "new" home dialysis patients, regardless of patient age, vintage, or payer. Only 2,812 of the 5,781 facilities across the two participating DOs had "new" home dialysis patients to contribute to the denominator and were included in the analysis.
    - The developer reports that LDO's facility-level performance scores were directly shared in follow-up webinars and other communications, as needed. Further, the developer states that participating facilities and DOs reported that interpretation of performance scores was intuitive, and results were consistent with internally tracked performance.

***Questions for the Standing Committee**:*

- *How have (or can) the performance results be used to further the goal of high quality, efficient healthcare?*
- *How has the measure been vetted in real-world settings by those being measured or others?*

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4b1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluates the extent to which audiences (e.g., consumers, purchasers, providers, and policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- The measure has not yet been implemented in a public reporting program, so improvement cannot be evaluated. However, the developer states that the adoption of the measure in the ETC Model would increase the utilization of home dialysis among individuals with ESRD who require dialysis.

4b2. Benefits versus harms. The benefits of the performance measure in facilitating progress toward achieving high quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- The developer did not report any unexpected findings as the measure has not been implemented yet.

Potential harms

- The developer did not report any potential harm as the measure has not been implemented yet.

***Questions for the Standing Committee**:*

- *How can the performance results be used to further the goal of high quality, efficient healthcare?*
- *Do the benefits of the measure outweigh any potential unintended consequences?*

Preliminary rating for Usability and Use: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Criterion 5: Related and Competing Measures

Related Measures

- The developer noted one non-NQF endorsed measure that is related to this measure.
    - Home Dialysis Rate

Harmonization

- The developer stated that they harmonized this measure with other non-NQF endorsed measures to the extent possible.

Criteria 1: Importance to Measure and Report

1a. Evidence

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]

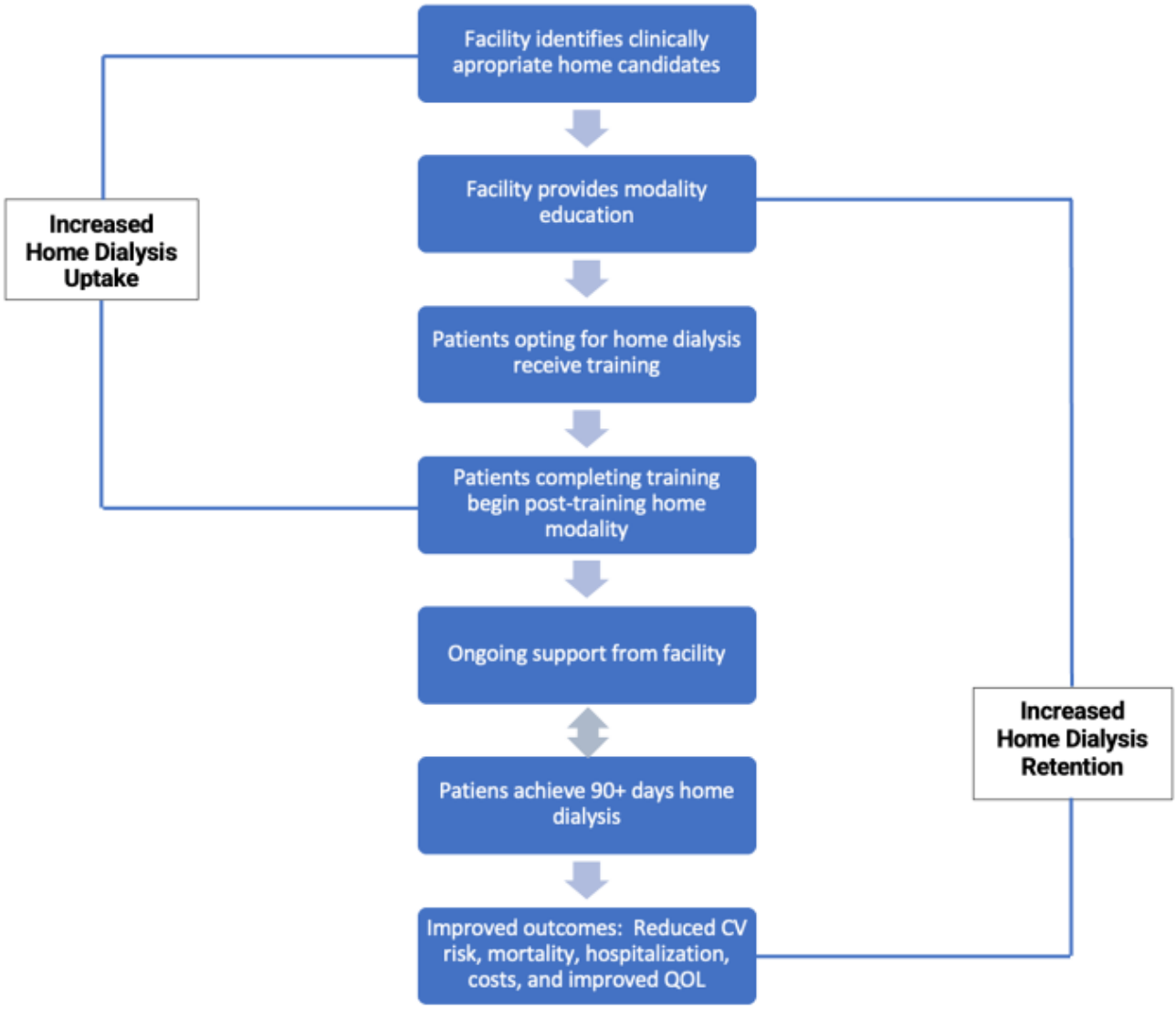
Accordingly, increasing home dialysis is a major objective of the Advancing American Kidney Health Initiative and the ensuing ESRD Treatment Choices (ETC) Payment Model, launched by the Centers for Medicare & Medicaid Services (CMS) in January 2021.[9] The model is intended to encourage greater use of 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.

KCQA's Home Dialysis Measure 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 set pairs a "core" Home Dialysis Rate Measure, intended to incentivize home prescription, with a "guardrail" Home Dialysis Retention Measure to counterbalance unopposed incentivization and to minimize 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 basic premise of the measure set 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 is being measured and how the measure components are connected to patient health outcomes.

HOME DIALYSIS RETENTION LOGIC MODEL



Specifically, adoption of the Home Dialysis Retention Measure will incentivize the facility to implement process interventions (e.g., effective modality education, appropriate patient preparation/training/support) to improve home dialysis retention among patients who have selected and commenced a home modality.

As noted in our accompanying KCQA Home Dialysis Rate Measure (NQF 3722) submission, while the Rate Measure can stand alone, we recommend it be paired with the 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.[10] 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.[11] 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. 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.

NOTES:

- 90 days was identified by our Expert Workgroup and Steering Committee as an appropriate retention goal that will serve to foster proper investment in patient support and preparation for the transition home, but is not so formidable a time requirement that it will discourage home trials in all but the most ideal candidates.
- *Consecutive* months on home dialysis are required to discourage attempts to meet the 90-day criterion cumulatively through sporadic, repeated starts in potentially inappropriate candidates.
- The consecutive time count is carried forward into the subsequent calendar year for patients who commence home dialysis late in the measurement year to ensure all patients meeting numerator criteria are captured.
- Unlike the "all-patient" construct of the Rate Measure, the Retention Measure only captures *new* home dialysis patients, such that only facilities offering/providing home dialysis in the measurement year are captured in the measure's denominator. As such, aggregating up to the Dialysis Organization's Hospital Referral Region (HRR)-level performance to account for facilities that do *not* offer home dialysis is unnecessary with this measure. **Within the context of the HRR-based ETC Program, the Retention Measure** would be evaluating individual facilities that provide home dialysis within the aggregate groups.
- Unlike the "patient-month" construct of the Rate Measure, the Retention Measure instead uses a "patient construct" because patient's contributed time has no intrinsic value *per se* for the dichotomous outcome being assessed (e.g., patients either did or did not achieve 90 consecutive days of home dialysis during the measurement year).

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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. 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.)
11. Include link to Lori's letter here.

[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 or retention. As such, evidence for the KCQA Home Dialysis Measures is based on a large body of observational studies in the U.S. 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*) 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 percent.[1,2] Barriers to home dialysis utilization and growth are multifactorial:[3]

- Patient factors include a lack of patient awareness and/or education/training, 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]

Home dialysis retention is a challenge. While introducing patients to home therapy is productive, keeping patients on home dialysis long term remains a challenge. According to the USRDS, 25% of patients who initiated home hemodialysis in 2017 to 2018 had converted to in-center hemodialysis after 2 years. The corresponding conversion with peritoneal dialysis was 24%, according to the 2021 data report.[21]

Attrition is greatest in the first 3-4 months. While there is a general paucity of studies looking at the timeline within which patients who experience a home treatment failure return to in-center care, there are a handful of publications indicating that the attrition rate is in fact highest during the first 3-4 months of treatment for both peritoneal and home hemodialysis patients.[22,23,24] This was corroborated as accurate by both our Expert Workgroup and Steering Committee.

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.[25] 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.[26] The KCQA Home Dialysis Measures were conceptualized and developed to fill that role.

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[Response Ends]

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

[Response Begins]

A literature search of ESKD 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 and attrition;
- 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 46 unique articles.

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.
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[Response Ends]

1b. Gap in Care/Opportunity for Improvement and Disparities

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]

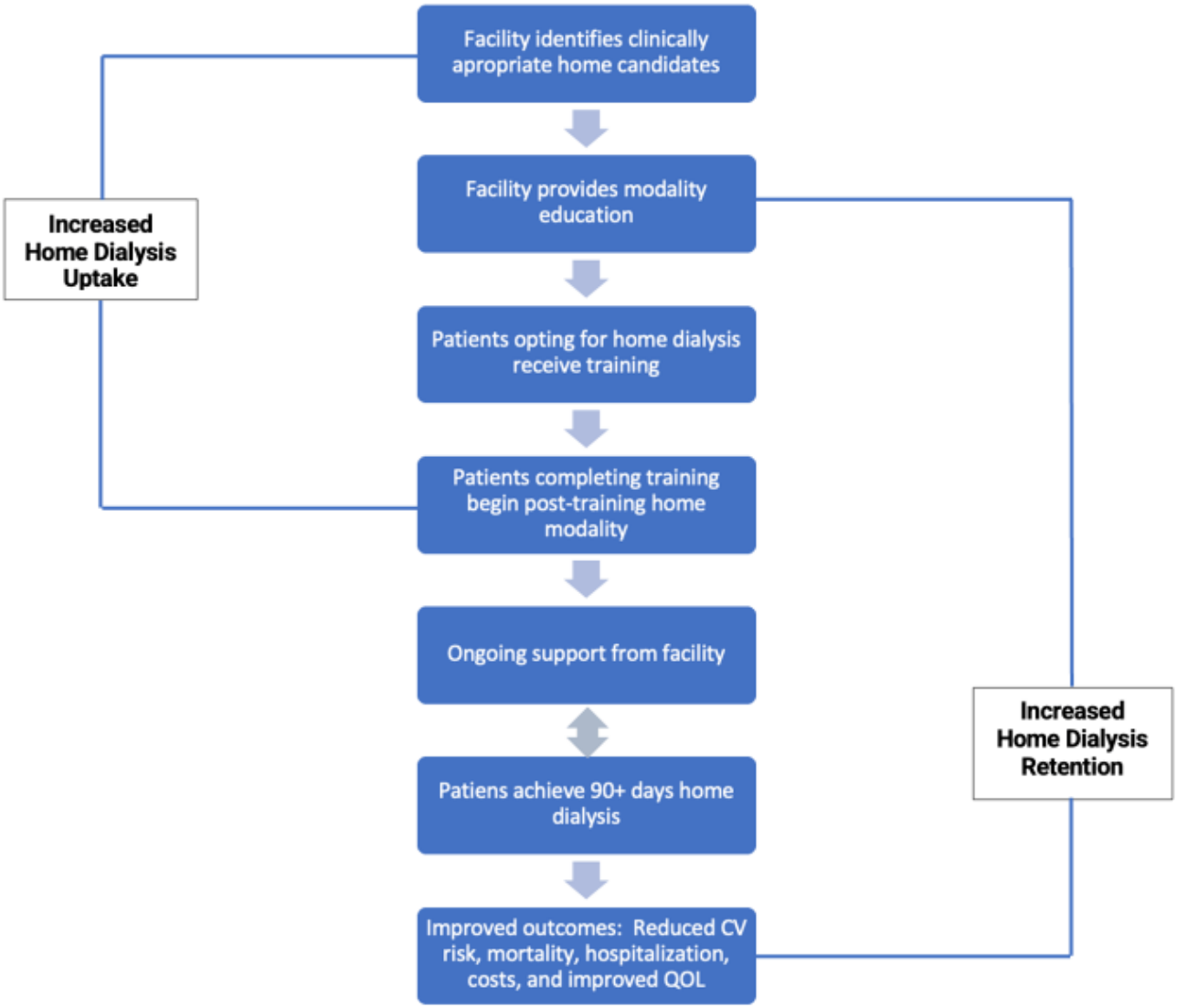
As previously noted, dialysis modality selection impacts both clinical and patient-reported outcomes.[1] While PD yields similar short- and long-term survival to in-center HD for individuals with ESKD,[2] PD enhances patient autonomy and quality of life, is associated with preservation of residual kidney 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.

KCQA's Home Dialysis Measure 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 basic premise of the measure set 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 is being measured and how the measure components are connected to patient health outcomes.

HOME DIALYSIS RETENTION LOGIC MODEL



Specifically, adoption of the Home Dialysis Retention Measure will incentivize the facility to implement process interventions (e.g., effective modality education, appropriate patient preparation/training/support) to improve home dialysis retention among patients who have selected and commenced a home modality.

As noted in our accompanying KCQA Home Dialysis Rate Measure (NQF 3722) submission, while the Rate Measure can stand alone, we recommend it be paired with the 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.[11] 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. 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.

References

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. 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]

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 at the individual facility level.[1] Within the context of the HRR-based ETC Program, the Retention Measure would be evaluating individual facilities that provide home dialysis within the aggregate groups. Performance scores were calculated during measure testing at the facility level. Testing encompassed 30,549 eligible[1] "new"[2] home dialysis patients, regardless of patient age, vintage, or payer. Only 2,812 of the 5,781 facilities across the two participating DOs had "new" home dialysis patients to contribute to the denominator and were included in the analysis. The overall distributions and deciles of performance scores are summarized in the following table:[3]

N of facilities	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
2,812	74.7	30.5	0.0	68.8	83.3	100.0	100.0	0.0	62.5	75.0	80.0	88.9	94.1	100.0	100.0

As can be seen, facility-level performance in our testing data reveals a mean facility performance of under 75% (range of 0-100%), confirming both considerable room for improvement in this aspect of care and marked performance variation across facilities.

References:

1. Unlike the "all-patient" construct of the accompanying Home Dialysis Rate Measure, the Retention Measure only captures *new* home dialysis patients, such that only facilities offering/providing home dialysis in the measurement year are captured in the measure's denominator. As such, aggregating up to the Dialysis Organization's HRR-level performance to account for facilities that do *not* offer home dialysis is unnecessary with this measure.
2. Eligibility Criterion: To account for the requisite home dialysis training period (up to 4 weeks for home hemodialysis), wherein a certain proportion of patients can be expected to drop out before completion, new home dialysis patients are not eligible for inclusion in the denominator until Day 30 following their first home dialysis treatment, at which time the consecutive time count towards the numerator criterion commences. The rationale for this "eligibility criterion" is to avoid creating a disincentive for a home dialysis trial by penalizing providers for treatment failures during this training period.
3. New patients are defined as those who started a home dialysis modality during the given measurement year (i.e., between January 1 and December 31, 202X).
4. Unlike the all-patient construct of the accompanying Home Dialysis Rate Measure, the Home Dialysis Retention Measure **only captures *new* home dialysis patients**. Thus, as only facilities offering/providing home dialysis in the measurement year are captured in the Retention Measure denominator, aggregating performance up to the Dialysis Organization's Hospital Referral Region (HRR) unit to account for facilities that do ***not*** offer home dialysis is both unnecessary and meaningless. As such, the Retention Measure is calculated at the facility level only.

[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]

N/A.

[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. Stratified analyses of performance demonstrate that there is a clear trend by age (with patients under 18 achieving 90 or more days of home dialysis more consistently than older age groups), differences by race (with higher performance in "Other" races than in Black or White patients) and ethnicity (with Hispanics performing more than 7% higher than non-Hispanics), and by insurance status (with dual-eligible patients performing slightly better than non-dual-eligible patients):

*	White	Black	Other	Non-Hispanic	Hispanic	Dual Eligible	Not Dual Eligible
Mean Retention Rates	77.3	78.9	81.8	75.2	82.8	79.1	76.5

*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]

N/A.

[Response Ends]

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability

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 Retention

[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 new home dialysis patients in the measurement year for whom >=90 consecutive days of home dialysis was achieved.

[Response Ends]

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

[Response Begins]

The accompanying KCQA Home Dialysis Rate Measure can stand alone; however, we recommend it be paired with the 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: 3725_3725_Home Dialysis Retention 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]

Patients from the denominator who achieved >=90 consecutive days of home dialysis in the measurement year.

[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 count includes all patients from the denominator with "Dialysis Setting"[1] recorded as "Home" for >=90 consecutive days[2,3] at any time during the measurement year.

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	EQRS/CROWNWeb	1-Home, 2-Dialysis Facility/Center, 3-SNF/Long Term Care Facility
Home Dialysis Start Date	EQRS/CROWNWeb	Date
Facility CCN#	EQRS/CROWNWeb	CROWNWeb Facility Unique Identifier

References:

1. Patients with missing "Dialysis Setting" are counted in the denominator, but not the numerator. (I.e., missing dialysis setting is counted as in-center.)
2. The numerator consecutive time count is carried *forward* into the subsequent calendar year for patients who commence home dialysis after October 2 of the measurement year. (E.g., To determine if a patient who started home dialysis on November 1, 2021 met the 90-day numerator criterion, it is necessary to look through January 30, 2022.)
3. To differentiate home dialysis pauses secondary to respite and hospitalizations from true treatment failures, the count of consecutive time contribution toward the numerator and denominator will resume uninterrupted for patients with a home dialysis pause of <=30 days. (E.g., if a patient achieved 60 consecutive days of home dialysis, then was hospitalized for 15 days and resumed home therapy upon hospital discharge, the consecutive count would begin again at Day 61.)

[Response Ends]

sp.15. State the denominator.

Brief, narrative description of the target population being measured.

[Response Begins]

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

[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 eligible[1] new[2] home dialysis patients attributed[3] to the dialysis facility[4] during the measurement year according to each patient's treatment history.

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)
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
Home Dialysis Start Date	EQRS/CROWNWeb	Date
Facility CCN #	CMS data sources	CROWN Facility Unique Identifier

References:

1. Eligibility Criterion: To account for the requisite home dialysis training period (up to 4 weeks for home hemodialysis), wherein a certain proportion of patients can be expected to drop out before completion, new home dialysis patients are not eligible for inclusion in the denominator until Day 30 following their first home dialysis treatment, at which time the consecutive time count towards the numerator criterion commences. The rationale for this "eligibility criterion" is to avoid creating a disincentive for a home dialysis trial by penalizing providers for treatment failures during this training period.
2. New patients are defined as those who started a home dialysis modality during the given measurement year (i.e., between January 1 and December 31, 202X).
3. 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. (As previously noted, in this instance the count towards the 90 consecutive numerator days continues uninterrupted —i.e., if the 90 consecutive days count is achieved within the first 30 days following the transfer, the original facility receives credit; if the count is achieved after 30 days following transfer, the destination facility receives credit.)
    - 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 continuous treatment is achieved an any one facility.
4. Unlike the all-patient construct of the accompanying Home Dialysis Rate Measure, the Home Dialysis Retention Measure *only captures **new** home dialysis patient*s. Thus, as only facilities offering/providing home dialysis in the measurement year are captured in the Retention Measure denominator, aggregating performance up to the Dialysis Organization's Hospital Referral Region (HRR) unit to account for facilities that do *not* offer home dialysis is both unnecessary and meaningless. As such, the Retention Measure is calculated at the facility level only.

[Response Ends]

sp.17. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

[Response Begins]

Denominator patients who are discharged from the facility for any of the following events occurring <90 days after meeting the 30-day eligibility criterion[1] are excluded:[2]

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

References:

1. To account for the requisite home dialysis training period (up to 4 weeks for home hemodialysis), wherein a certain proportion of patients can be expected to drop out before completion, new home dialysis patients are not eligible for inclusion in the denominator until Day 30 following their first home dialysis treatment, at which time the consecutive time count towards the numerator criterion commences. The rationale for this "eligibility criterion" is to avoid creating a disincentive for a home dialysis trial by penalizing providers for treatment failures during this training period.
2. The exclusions are intended to avoid disincentivizing home dialysis trials by penalizing providers for unanticipated events beyond their realm of control that prevented a patient from achieving the 90 day numerator criterion.

[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]

Patients captured in the denominator count will be excluded if discharged from the facility for any of the following events occurring <90 days after meeting the 30-day eligibility criterion:[1]

1. Transplant;
2. Death;
3. Discontinuation of dialysis;
4. Recovery of function;
5. Admission to hospice; and/or
6. Admission to nursing home or other LTCF.

The following data elements are required to identify the exclusions:

Exclusion	Data Element	Primary Data Source	Values
<90 Days Criterion	Home Dialysis Start Date	EQRS/CROWNWeb	Date
Discharge Criterion	Facility Discharge Date	EQRS/CROWNWeb	Date
Exclusions 1, 2, 3, 4	Discharge Reason	EQRS/CROWNWeb	1 - Death, 2 - Discontinue, 3 - Lost to Follow Up, 4 - Recover Function, 7 - Transplant in US, 8 - Transplant outside US
Exclusions 5 & 6	Discharge Disposition	EQRS/CROWNWeb	2-Hospice, 4-Long Term Care Facility, 5-Rehab Center, 6-Nursing Home

Exclusion	Data Element	Primary Data Source	Values
Exclusion 5	Hospice Status, Current Month	CMS Hospice file	Yes, No, Unknown

References:

1. To account for the requisite home dialysis training period (up to 4 weeks for home hemodialysis), wherein a certain proportion of patients can be expected to drop out before completion, new home dialysis patients are not eligible for inclusion in the denominator until Day 30 following their first home dialysis treatment, at which time the consecutive time count towards the numerator criterion commences. The rationale for this "eligibility criterion" is to avoid creating a disincentive for a home dialysis trial by penalizing providers for treatment failures during this training period.

[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
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

The Table Lists the Data Elements Required to Identify the Stratification Variables

Clarification 1 Requested by NQF: Can the developer clarify if ethnicity is exhaustive for all patients? Or will options 1-5 in CROWNWeb be able to be chosen instead of 6/7?

Response 1: Both race and ethnicity should be entered in CROWNWeb for all patients. However, as indicated in our testing data (see 2b.09), approximately 7.18% of patients in our measurement year were found to be missing race data and 7.38% were missing ethnicity data. Thus, in our testing data, neither race nor ethnicity data were exhaustive for all patients. We expect these stratification variables are more consistently available within CROWNWeb.

Clarification 2 Requested by NQF: It appears that ethnicity is missing for 10.2% (2,954/28,791) in the demographic table in 2a.06, but 2b. 09 appears to show this is missing for 6.7% of patients. Race is equivalently missing 10.2% in 2a.06 but shows 6.5% in 2b.09. Age and sex also do not match up with 2b.09. Please clarify.

Response 2: Note that the above patient characteristics include all patients captured in the "raw" denominator (i.e., prior to application of the measure exclusions). As in Question 2a.06, ethnicity data were missing for 2,954 of 28,791 *raw* denominator patients (10.2%). However, as is illustrated in Question 2b.09, the *final* denominator count dropped from 28,791 to 27,835 after the exclusions were applied; 2,055 patients in that final denominator population had missing ethnicity data (2,055/27,835 = 7.38% [corrected]). The same applies to the other stratification variables.

[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]

We stratify the measure results 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]

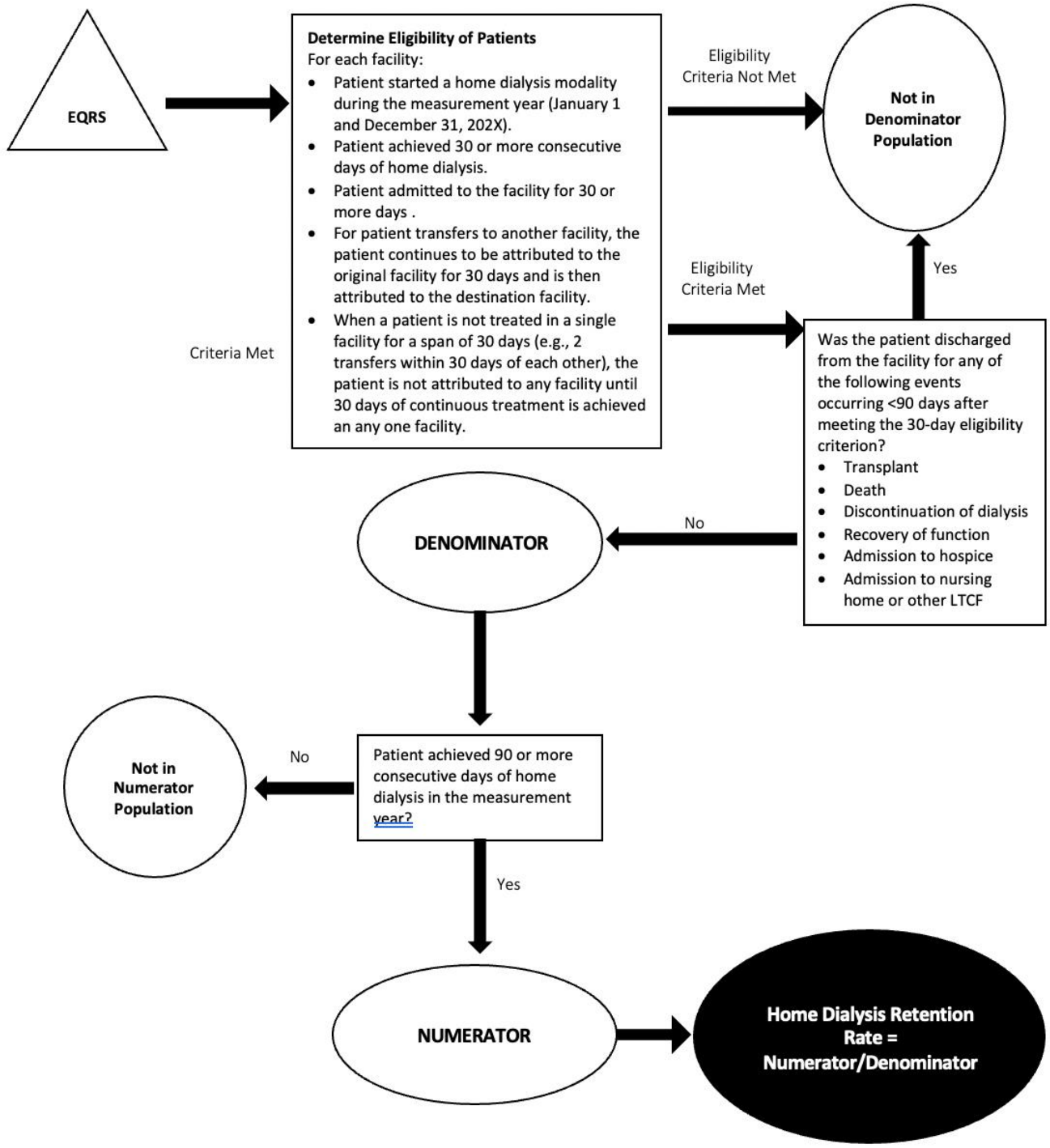
Better quality = Higher score

[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]



HOME DIALYSIS RETENTION CALCULATION FLOW CHART

Clarification Requested by NQF: Please clarify what is unable to be measured for Medicare Advantage patients in the absence of all but inpatient claims, if any? Same for non-Medicare patients with payment claims data.

Response: The Home Dialysis Measures rely on electronic clinical data collected on all dialysis patients, such that variations in claims data for Medicare Advantage and non-Medicare patients will have little impact on the measures.

[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.

Clarification Requested by NQF: Please clarify what is unable to be measured for Medicare Advantage patients in the absence of all but inpatient claims, if any? Same for non-Medicare patients with payment claims data.

Response: The Home Dialysis Measures rely on electronic clinical data collected on all dialysis patients, such that variations in claims data for Medicare Advantage and non-Medicare patients will have little impact on the measures.

[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 Retention 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 adult and pediatric new[1] home hemodialysis and peritoneal dialysis in all eligible facilities of the participating organizations during the testing period were included in our testing data.

Of note, unlike the all-patient construct of the accompanying Home Dialysis Rate Measure, the Home Dialysis Retention Measure only captures *new* home dialysis patients. Thus, as only facilities offering/providing home dialysis in the measurement year are captured in the Retention Measure denominator, aggregating performance up to the Dialysis Organization's Hospital Referral Region (HRR) unit to account for facilities that do *not* offer home dialysis is unnecessary. As such, the Retention Measure is calculated at the facility level only.

References:

1. "New" home dialysis patients are defined as those who started a home dialysis modality during the measurement year (i.e., between January 1 and December 31, 202X).

[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

[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. Only 2,812 of the 5,781 facilities in the two participating LDOs had "new" home dialysis patients to contribute to the denominator and were included in the analysis.

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
2,812	10	11	1	3	7	13	157	1	2	4	5	9	11	15	21

Thus, for the 2,812 facilities included in the analysis, the mean number of new home dialysis patients in the measurement year across both DOs was 10, with a range of 1 to 157 patients.

[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 across all participating facilities included in the analysis are displayed in the following table by age, sex, race, ethnicity, and dual eligible groups:

Stratification Variable	Patients	%
*	28,791	100.0
Age	*	*
0-<18	129	0.45
18-<25	550	1.91
25-<35	1,766	6.13
35-<45	3,315	11.51
45-<55	5,266	18.29
55-<65	6,498	22.57
65-<75	6,576	22.84
75-<85	3,255	11.31
>=85	537	1.87
Sex	*	*
Female	11,428	39.69
Male	16,470	57.21
Race	*	*
White	17,105	59.41
Black	6,681	23.21
Other	2,107	7.32
Ethnicity	*	*
Non-Hispanic	22,385	77.75
Hispanic	3,452	11.99
Dual Eligible	*	*
No	23,854	82.85
Yes	4,937	17.15

*Cell intentionally left blank.

Clarification 1 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?

Response 1: Both race and ethnicity should be entered in CROWNWeb for all patients. However, as indicated in our testing data (see 2b.09), approximately 7.18% of patients in our measurement year were found to be missing race data and 7.38% were missing ethnicity data. Thus, in our testing data, neither race nor ethnicity data were exhaustive for all patients. We expect these stratification variables are more consistently and readily available within CROWNWeb.

Clarification 2 Requested by NQF: It appears that ethnicity is missing for 10.2% (2,954/28,791) in the demographic table in 2a.06, but 2b. 09 appears to show this is missing for 6.7% of patients. Race is equivalently missing 10.2% in 2a.06 but shows 6.5% in 2b.09. Age and sex also do not match up with 2b.09. Please clarify.

Response 2: Note that the above patient characteristics include all patients captured in the "raw" denominator (i.e., prior to application of the measure exclusions). As above, ethnicity data were missing for 2,954 of 28,791 *raw* denominator patients (10.2%). However, as is illustrated in Question 2b.09, the *final* denominator count dropped from 28,791 to 27,835 after the exclusions were applied; 2,055 patients in that final denominator population had missing ethnicity data (2,055/27,835 = 7.38% [corrected]). The same applies to the other stratification variables.

[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 community characteristics and social risk data were not available for each patient; proxy 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+)
- 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 ratio of these estimates then produced an estimate of the reliability at each facility, 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:

$$reliability = \frac{\sigma^2_{provider\text{-}to\text{-}provider}}{\sigma^2_{provider\text{-}to\text{-}provider} + \sigma^2_{error}}$$

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

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

The distribution of reliability estimates across all facilities 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]

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

*	N of facilities	Mean	STD	Min	10th	Q1	Median	Q3	90th	Max	Alpha	Beta
All facilities	2,812	0.604	0.355	0.050	0.151	0.274	0.547	1.000	1.000	1.000	17.6811	3.9594

*Cell intentionally left blank.

While the above reliability statistics meet NQF's identified criterion, given the small numbers of new home dialysis patients in the measurement year contributed to the measure's denominator by some facilities (see 2a.05, above), we hypothesized that a rolling-year measure construct might further increase measure reliability. As we only had access to a single year of testing data (2021), we opted to test this hypothesis by "reusing" our 2021 data as a proxy for a second year of data to reassess our reliability statistics with a 2-year rolling-year construct. As predicted, the analyses indicate an improvement in measure reliability:

*	N of facilities	Mean	STD	Min	10th	Q1	Median	Q3	90th	Max
2021 data	2812	0.604	0.355	0.050	0.151	0.274	0.547	1.000	1.000	1.000
Duplicate 2021 data	2812	0.846	0.181	0.294	0.584	0.748	0.905	1.000	1.000	1.000

*Cell intentionally left blank.

In response to this concern, we performed the following analysis to demonstrate that "double use" of the 2021 data should provide a valid analysis: Instead of "double use the 2021 data", we randomly generated a new "yearly" data for each facility with the assumption that, in the new year, each facility had the same facility size (number of patients had home dialysis) and the same performance on retention of home dialysis for at least 90 days. We combined the 2021 data with the newly simulated yearly data and performed the same analysis as the "double use of 2021 data" analysis. We got the similar results as the "double use of 2021 data" analysis, as below:

We thus note the measure could be implemented using a 2-year rolling measure construct to further strengthen measure performance.

Clarification 1 Requested by NQF: Please clarify the method for doubling the sample? Did you duplicate the existing 2021 data without correction for repeated identical observations?

Response 1: In response to this concern, we performed the following analysis to demonstrate that "double use" of the 2021 data should provide a valid analysis: Instead of "double use the 2021 data", we randomly generated a new "yearly" data for each facility with the assumption that, in the new year, each facility had the same facility size (number of patients had home dialysis) and the same performance on retention of home dialysis for at least 90 days. We combined the 2021 data with the newly simulated yearly data and performed the same analysis as the "double use of 2021 data" analysis. The analysis yielded similar results to the "double use of 2021 data" analysis:

*	N of facilities	Mean	STD	Min	10th	Q1	Median	Q3	90th	Max
2021 data	2812	0.604	0.355	0.050	0.151	0.274	0.547	1.000	1.000	1.000
Duplicate 2021 data	2812	0.846	0.181	0.294	0.584	0.748	0.905	1.000	1.000	1.000
2021 data + randomly generated data	2812	0.871	0.159	0.340	0.635	0.786	0.931	1.000	1.000	1.000

*Cell intentionally left blank.

Interpretation of the supplemental analysis: While "double use" of data can raise the concern of correlation, we demonstrate that when the performance score spreads wide enough, the impact on reliability is minor.

Clarification 2 Requested by NQF: Please clarify if the 2 year rolling requirement will change any of the numerator/denominator criteria. For example, is a facility required to have two years of data before its patients can be included in the measure? Please clarify as appropriate.

Response 2: We note that as reliability is adequate with a single year of data, the 2-year construct is not strictly necessary. However, if CMS were to adopt the recommendation for a rolling 2-year construct, to yield consistent results for user interpretation we do recommend that all facilities should have two years of data for results to be reported on the measure.

[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 "acceptable" at 0.604 for the single-year measure and increases to "very good" at 0.846 with a 2-year construct. As such, we recommend the measure be implemented using a 2-year rolling measure construct.

[Response Ends]

2b. Validity

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]

Per NQF guidance,[1] face validity of the measure score as an indicator of quality 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 provider, two dialysis facility, and three manufacturer groups.[2] Panel members were provided the detailed measure specifications 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]

There was significant agreement among Expert Panel members that scores from the Retention Measure as specified will provide a fair and accurate assessment of quality and effectively distinguishes differences in performance between providers:

- 77.77% of Expert Panel Members (n=7 of 9) agreed it is highly likely or likely that the measure score will provide an accurate reflection of quality.
- 77.77% of Expert Panel Members (7 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 moderate level of agreement among Expert Panel Members that scores from the Retention Measure 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 this measure has good face validity.

There was a high level of agreement among Expert Panel Members that scores from the paired 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 the measure set has 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. 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]

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

N of facilities	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
2,812	74.7	30.5	0.0	68.8	83.3	100.0	100.0	0.0	62.5	75.0	80.0	88.9	94.1	100.0	100.0

The Table Illustrates the Distribution and Deciles of Measure Performance Scores, Rate as %

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

Score range	N	%	Cumulative N	Cumulative %
0	325	11.64	325	11.6
1-< 50%	50	1.79	375	13.4
50-<60%	134	4.8	509	18.2
60-<70%	211	7.56	720	25.8
70-<80%	375	13.43	1,095	39.2
80-<85%	341	12.21	1,436	51.4
85-<90%	268	9.6	1,704	61.0
90-<95%	218	7.81	1,922	68.8
>=95%	870	31.16	2,792	100.0

The Table Illsutrates the Distribution of Performance Scores

To demonstrate the statistical significance of the spread, we used the 2021 data plus the randomly generated data (as described above in the supplemental analysis in Section 2a.11) and performed the following analyses among 1,699 facilities (out of 2,812) with a performance score >0 and <100%.[1] The overall weighted mean performance score was 80.4% with the facility size as the weight (this is the national percent of new home dialysis with >=90 consecutive days). We call this the national norm. The distribution of performance scores among the 1,699 facilities is as below:

Deciles	Min	5th	10th	20th	30th	40th	50th	60th	70th	80th	90th	95th	Max
Performance score	6.25	50.00	52.87	66.67	72.92	76.92	80.00	83.33	87.50	90.00	92.86	95.00	98.53

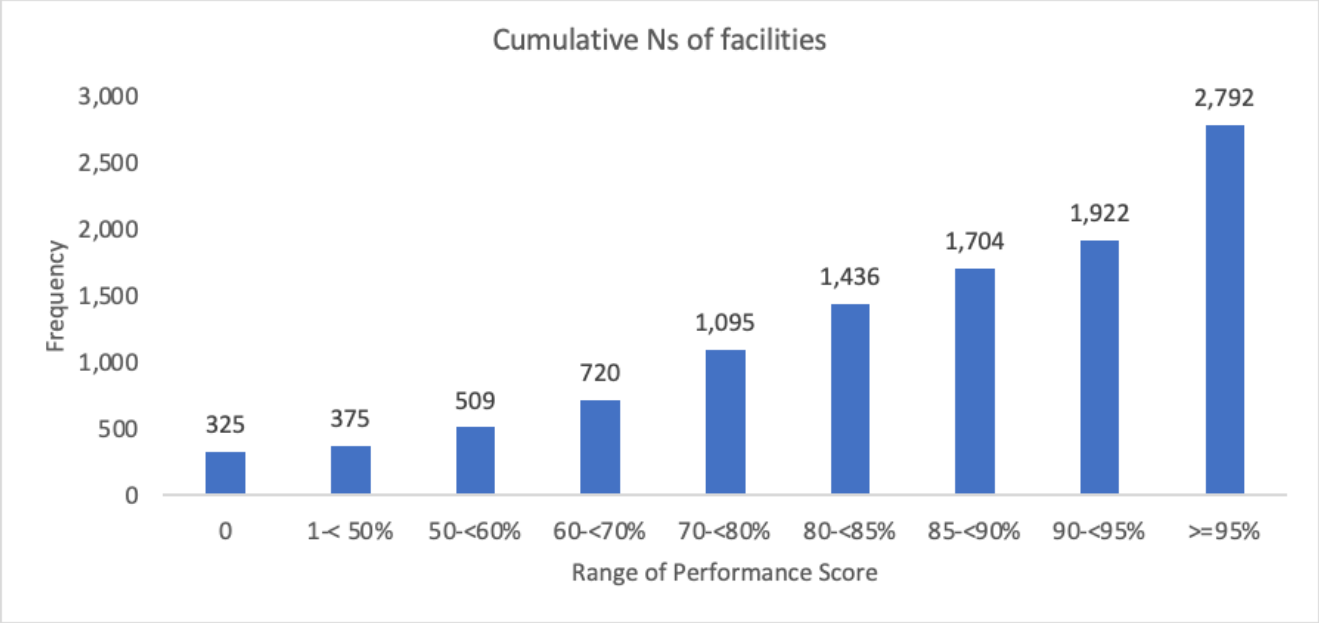
The Table Illustrates the Distribution of Performance Scores

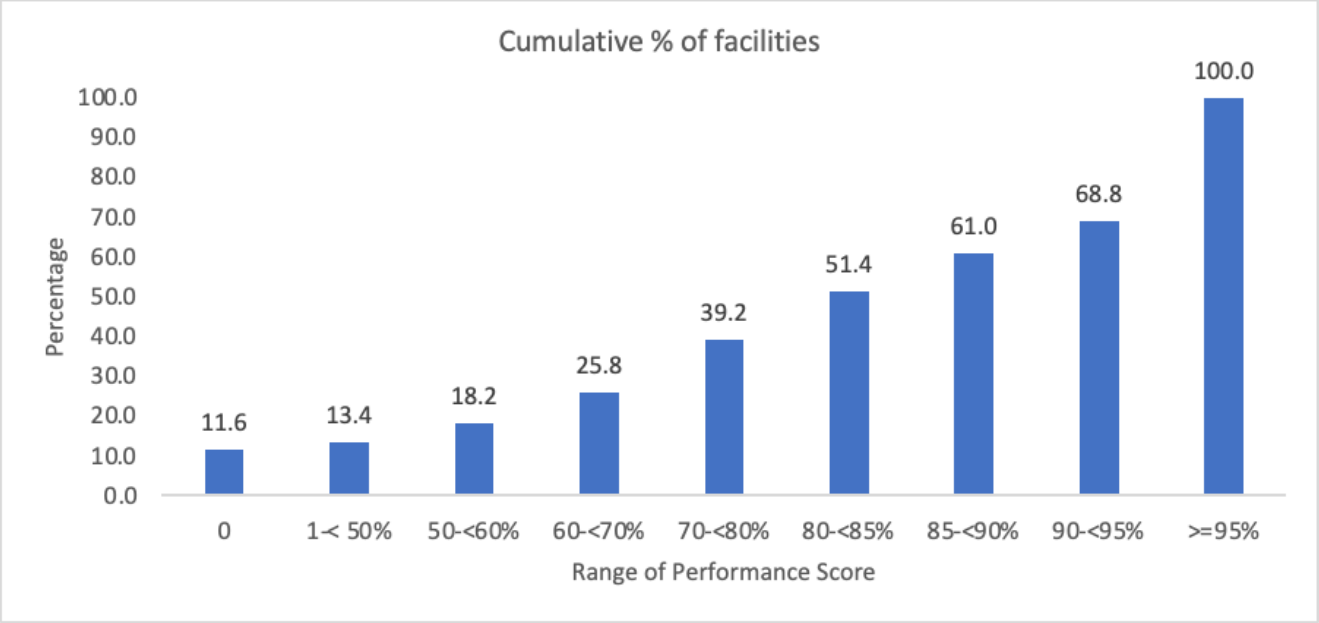
We then grouped the facilities based on deciles of performance score and calculated the 95% confidence interval (CI) of performance score for each facility. If the 95% CI of a facility does not include the national norm, then the performance score of the facility was statistically different from the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

- Among 170 facilities with a score between 6.25% (min) and 52.87% (the 10th decile), 60% (102 facilities) had 95% CIs below the norm.
- Among 164 facilities with a score >92.86% (the 90th decile) to 98.53% (max), all had 95% CIs above the norm.

These results indicate that the measure performance scores can readily identify facilities with "good" performance; however, identification of facilities with "poor" performance was more variable, which we believe is a result of small facility size. For example, all 68 of the facilities for which the national norm fell within the 95% CI had 10 or fewer patients.

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





References/Notes:

1. In the current data, there are some facilities with 0 or 100% performance score (i.e., percent of all new home dialysis patients in the measurement year for whom >=90 consecutive days of home dialysis was achieved).

[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]

The above results show that there are statistical and practical differences in performance between facilities, with a significant spread demonstrated between minimum and maximum scores, the mean/median and minimum and maximum scores, and various deciles of performance.

Likewise, measure performance scores can readily identify facilities with "good" performance; however, identification of facilities with "poor" performance was more variable, which we believe is a result of small facility size. For example, all 68 of the facilities for which the national norm fell within the 95% CI had 10 or fewer patients.

[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 of home dialysis patients, home dialysis start date, 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%) is not accurate. 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 (0.5%) 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 (1%), our final denominator would decrease from 27,835 to 27,611 patients, increasing our overall facility-level score from 74.7% to approximately 75.3%, a difference of only 0.4%.

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	Ns	%
Missing age	6	0.02%
Missing sex	0	0.00%
Missing race	1,999	7.18%
Missing ethnicity	2,055	7.38%
Missing dual eligibility	0	0.00%

As above, missing values were quite small and had little effect on measure scores. When patients were excluded from the denominator due to missing values in stratification variables, mean performance scores were 74.7% and 74.8% before and after excluding all patients with missing values. The median of performance was unchanged at 83.3%.

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 ethnicity is missing for 10.2% (2,954/28,791) in the demographic table in 2a.06, but 2b. 09 appears to show this is missing for 6.7% of patients. Race is equivalently missing 10.2% in 2a.06 but shows 6.5% in 2b.09. Age and sex also do not match up with 2b.09. Please clarify.

Response: Note that the above patient characteristics include all patients captured in the "final" denominator (i.e., after application of the measure exclusions). While in Question 2a.06, ethnicity data were missing for 2,954 of 28,791 *raw* denominator patients (10.2%), the above values represent the *final* denominator count, which dropped from 28,791 to 27,835, after the exclusions were applied. 2,055 patients in that final denominator population had missing ethnicity data (2,055/27,835 = 7.38% [corrected]). The same applies to the other stratification variables.

[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 and will not introduce significant bias.

[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]

Patients are excluded from the annual denominator count if discharged from their treating facility prior to achieving 90 consecutive days of home dialysis secondary to transplant, death, discontinuation of dialysis, recovery of function, enrollment in hospice, admission to a nursing home or other LTCF.[1]

We examined the distribution of the number and relative frequency of excluded patients, then calculated and compared the facility-level mean home dialysis retention rate with and without the exclusions.

Reference

1. Pertinent exclusions are reapplied in the Retention Measure to ensure providers aren't inappropriately penalized for favorable (e.g., transplant) or unforeseen outcomes (e.g., death, discontinuation of dialysis) occurring after commencement of home dialysis but before 3 consecutive months of treatment could be achieved.

[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.

*	N of total home dialysis (HD) patients	% of patients removed from "New" HD patients	N of facilities
a. Home Dialysis Patients	87,904	*	3,404
b. "New" Home Dialysis Patients	30,549	100%	2,892
c. Patients Meeting Denominator Attribution Criterion**	28,791	*	2,820
d. Patients Meeting Exclusion Criteria:	*	*	*
i. Discharged from the facility due to transplantation.	125	0.4%	*
ii. Discharged from the facility due to death.	548	1.8%	*
iii. Discharged from the facility due to discontinuation of dialysis.	160	0.5%	*
iv. Discharged from the facility due to recovery of renal function.	39	0.1%	*
v. Admission to/enrollment in hospice.	0	0.0%	*
vi. Admission to/residing in a nursing home of other LTCF.	308	1.0%	*
Total exclusions^	956	3.1%	*
Final Denominator (after exclusions applied)^^	27,835	*	2,812

*Cell intentionally left blank.

**Achieved >=30 days of continuous home dialysis treatment at the facility following their Home Dialysis Start Date

^Total exclusions of patients are not equal to the sum of above exclusions because some patients may have more than one excluding condition.

^^Some denominator patients have missing values in stratification variables.

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

*	N of facilities	Mean	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Before exclusions applied	2,820	72.4	30.3	0.0	66.7	80.0	93.8	100.0	0.0	60.0	70.0	75.0	85.7	90.0	100.0	100.0
After exclusions applied	2,812	74.7	30.5	0.0	68.8	83.3	100.0	100.0	0.0	62.5	75.0	80.0	88.9	94.1	100.0	100.0

*Cell intentionally left blank.

[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 3.1% of all patients are removed from the denominator population with application of all exclusions, appreciably impacting mean performance (~2.5% change). However, the overall frequency of the individual exclusions is low, with death accounting for the most exclusions at 1.8%. Nevertheless, we believe all original exclusions should be retained to avoid creating a disincentive for home dialysis trials by penalizing providers for unanticipated events beyond their realm of control that prevented a patient from achieving the 90 day numerator criterion:

- Discharge due to death (1.8%): Home dialysis is no longer relevant.
- Discharge due to transplant (0.4%): Home dialysis is no longer relevant.
- Discharge due to discontinuation of dialysis (0.5%): Home dialysis is no longer relevant.
- Discharge due to recovery of function (0.1%): Home dialysis is no longer relevant.
- Discharge to/admission to hospice (0% [see missing data consideration discussed previously]): Limited life expectancy; financial incentivization of home dialysis prescription not appropriate.
- Discharge to/admission to nursing home/LTCF (1%): Complex, vulnerable patient population with frequent and multiple co-morbidities, many with limited life expectancy; financial incentivization of home dialysis prescription not appropriate.

[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 Retention 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	2,812	74.7	30.5	0.0	68.8	83.3	100.0	100.0	0.0	62.5	75.0	80.0	88.9	94.1	100.0	100.0

*	N of Facilities	**Mean**	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Age	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
0-<18	59	91.9	25.9	0.0	100.0	100.0	100.0	100.0	83.3	100.0	100.0	100.0	100.0	100.0	100.0	100.0
18-<25	432	75.6	40.9	0.0	50.0	100.0	100.0	100.0	0.0	0.0	100.0	100.0	100.0	100.0	100.0	100.0
25-<35	1,058	81.7	34.9	0.0	85.7	100.0	100.0	100.0	0.0	60.0	100.0	100.0	100.0	100.0	100.0	100.0
35-<45	1,465	82.4	32.1	0.0	75.0	100.0	100.0	100.0	0.0	66.7	90.0	100.0	100.0	100.0	100.0	100.0
45-<55	1,876	81.6	31.3	0.0	75.0	100.0	100.0	100.0	33.3	66.7	80.0	100.0	100.0	100.0	100.0	100.0
55-<65	2,063	80.9	30.5	0.0	66.7	100.0	100.0	100.0	33.3	63.6	75.0	100.0	100.0	100.0	100.0	100.0
65-<75	2,082	79.8	31.8	0.0	66.7	100.0	100.0	100.0	0.0	60.0	75.0	90.9	100.0	100.0	100.0	100.0
75-<85	1,549	78.5	35.2	0.0	66.7	100.0	100.0	100.0	0.0	50.0	75.0	100.0	100.0	100.0	100.0	100.0
>=85	418	80.9	37.3	0.0	100.0	100.0	100.0	100.0	0.0	50.0	100.0	100.0	100.0	100.0	100.0	100.0
Sex	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Female	2,416	78.6	30.4	0.0	66.7	93.9	100.0	100.0	33.3	60.0	75.0	82.4	100.0	100.0	100.0	100.0
Male	2,591	77.5	29.9	0.0	66.7	87.5	100.0	100.0	33.3	63.6	75.0	80.0	100.0	100.0	100.0	100.0
Race	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
White	2,509	77.3	29.4	0.0	66.7	85.7	100.0	100.0	33.3	66.7	75.0	80.0	93.3	100.0	100.0	100.0
Black	1,679	78.9	32.4	0.0	66.7	100.0	100.0	100.0	0.0	60.0	75.0	86.7	100.0	100.0	100.0	100.0
Other	878	81.8	34.5	0.0	80.0	100.0	100.0	100.0	0.0	66.7	100.0	100.0	100.0	100.0	100.0	100.0
Ethnicity	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Non-Hispanic	2,714	75.2	30.9	0.0	66.7	84.3	100.0	100.0	0.0	62.5	72.7	80.0	90.0	100.0	100.0	100.0

*	N of Facilities	**Mean**	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
Hispanic	1,121	82.8	31.5	0.0	75.0	100.0	100.0	100.0	0.0	66.7	85.7	100.0	100.0	100.0	100.0	100.0
Dual Eligible	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
No	2,723	76.5	29.6	0.0	68.4	85.7	100.0	100.0	20.0	66.7	75.0	80.0	90.3	100.0	100.0	100.0
Yes	1,811	79.1	33.2	0.0	66.7	100.0	100.0	100.0	0.0	50.0	75.0	100.0	100.0	100.0	100.0	100.0

*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 of performance demonstrate that there is a clear trend by age (with patients under 18 achieving 90 or more days of home dialysis more consistently than older age groups), differences by race (with higher performance in "Other" races than in Black or White patients) and ethnicity (with Hispanics performing more than 7% higher than non-Hispanics), and by insurance status (with dual-eligible patients performing slightly better than non-dual-eligible patients).

While risk-adjustment might obscure these variations, 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 Retention 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 the facility level.

[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	2,812	74.7	30.5	0.0	68.8	83.3	100.0	100.0	0.0	62.5	75.0	80.0	88.9	94.1	100.0	100.0
Age	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
0-<18	59	91.9	25.9	0.0	100.0	100.0	100.0	100.0	83.3	100.0	100.0	100.0	100.0	100.0	100.0	100.0
18-<25	432	75.6	40.9	0.0	50.0	100.0	100.0	100.0	0.0	0.0	100.0	100.0	100.0	100.0	100.0	100.0
25-<35	1,058	81.7	34.9	0.0	85.7	100.0	100.0	100.0	0.0	60.0	100.0	100.0	100.0	100.0	100.0	100.0

*	N of Facilities	**Mean**	STD	Min	Q1	Median	Q3	Max	10th	20th	30th	40th	60th	70th	80th	90th
35-<45	1,465	82.4	32.1	0.0	75.0	100.0	100.0	100.0	0.0	66.7	90.0	100.0	100.0	100.0	100.0	100.0
45-<55	1,876	81.6	31.3	0.0	75.0	100.0	100.0	100.0	33.3	66.7	80.0	100.0	100.0	100.0	100.0	100.0
55-<65	2,063	80.9	30.5	0.0	66.7	100.0	100.0	100.0	33.3	63.6	75.0	100.0	100.0	100.0	100.0	100.0
65-<75	2,082	79.8	31.8	0.0	66.7	100.0	100.0	100.0	0.0	60.0	75.0	90.9	100.0	100.0	100.0	100.0
75-<85	1,549	78.5	35.2	0.0	66.7	100.0	100.0	100.0	0.0	50.0	75.0	100.0	100.0	100.0	100.0	100.0
>=85	418	80.9	37.3	0.0	100.0	100.0	100.0	100.0	0.0	50.0	100.0	100.0	100.0	100.0	100.0	100.0
Sex	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Female	2,416	78.6	30.4	0.0	66.7	93.9	100.0	100.0	33.3	60.0	75.0	82.4	100.0	100.0	100.0	100.0
Male	2,591	77.5	29.9	0.0	66.7	87.5	100.0	100.0	33.3	63.6	75.0	80.0	100.0	100.0	100.0	100.0
Race	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
White	2,509	77.3	29.4	0.0	66.7	85.7	100.0	100.0	33.3	66.7	75.0	80.0	93.3	100.0	100.0	100.0
Black	1,679	78.9	32.4	0.0	66.7	100.0	100.0	100.0	0.0	60.0	75.0	86.7	100.0	100.0	100.0	100.0
Other	878	81.8	34.5	0.0	80.0	100.0	100.0	100.0	0.0	66.7	100.0	100.0	100.0	100.0	100.0	100.0
Ethnicity	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Non-Hispanic	2,714	75.2	30.9	0.0	66.7	84.3	100.0	100.0	0.0	62.5	72.7	80.0	90.0	100.0	100.0	100.0
Hispanic	1,121	82.8	31.5	0.0	75.0	100.0	100.0	100.0	0.0	66.7	85.7	100.0	100.0	100.0	100.0	100.0
Dual Eligible	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
No	2,723	76.5	29.6	0.0	68.4	85.7	100.0	100.0	20.0	66.7	75.0	80.0	90.3	100.0	100.0	100.0
Yes	1,811	79.1	33.2	0.0	66.7	100.0	100.0	100.0	0.0	50.0	75.0	100.0	100.0	100.0	100.0	100.0

*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 of performance demonstrate that there is a clear trend by age (with patients under 18 achieving 90 or more days of home dialysis more consistently than older age groups), differences by race (with higher performance in "Other" races than in Black or White patients) and ethnicity (with Hispanics performing more than 7% higher than non-Hispanics), and by insurance status (with dual-eligible patients performing slightly better than non-dual-eligible patients).

While risk-adjustment might obscure these variations, 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 Retention 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; measure is not risk-adjusted.

[Response Ends]

Criterion 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]

Criterion 4: Use and Usability

4a. 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 the facility level.[1] Testing encompassed 30,549 eligible[2] "new"[3] home dialysis patients, regardless of patient age, vintage, or payer. Only 2,812 of the 5,781 facilities across the two participating DOs had "new" home dialysis patients to contribute to the denominator and were included in the analysis.

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-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.

References

2. Unlike the "all-patient" construct of the accompanying Home Dialysis Rate Measure, the Retention Measure only captures *new* home dialysis patients, such that only facilities offering/providing home dialysis in the measurement year are captured in the measure's denominator. As such, aggregating up to the Dialysis Organization's HRR-level performance to account for facilities that do *not* offer home dialysis is unnecessary with this measure. **Within the context of the HRR-based ETC Program, the Retention Measure** would be evaluating individual facilities that provide home dialysis within the aggregate groups.
3. To account for the requisite home dialysis training period (up to 4 weeks for home hemodialysis), wherein a certain proportion of patients can be expected to drop out before completion, new home dialysis patients are not eligible for inclusion in the denominator until Day 30 following their first home dialysis treatment, at which time the consecutive time count towards the numerator criterion commences. The rationale for this "eligibility criterion" is to avoid creating a disincentive for a home dialysis trial by penalizing providers for treatment failures during this training period.
4. New patients are defined as those who started a home dialysis modality during the given measurement year (i.e., between January 1 and December 31, 202X).

[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-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 or 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-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. Usability

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 adopt 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) the Rate Measure is intended to be paired with this 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 and 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.

References

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]

Criterion 5: Related and 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 Measure Set 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 measures are 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 patients discharged from the facility <90 days after meeting the 30-day eligibility criterion[4] for transplant, death, discontinuation of dialysis, recovery of function, admission to hospice, and/or admission to nursing home or other LTCF. The rationale for these exclusions is to avoid creating a disincentive for a home dialysis trial by penalizing providers for events beyond their control.
- Finally, we note that while the accompanying KCQA Home Dialysis Rate Measure can stand alone, we recommend it be paired with the 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 patient 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.

Reference

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. (See Figure 2.11.)

[Response Ends]