NATIONAL QUALITY FORUM
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Meeting Summary

Renal Standing Committee – Measure Evaluation Web Meeting

The National Quality Forum (NQF) convened the Renal Standing Committee for a web meeting on February 10, 2023, to evaluate three renal measures for the fall 2022 cycle.

Welcome, Review of Meeting Objectives, Introductions, and Overview of Evaluation and Voting Process

Leah Chambers, NQF director, welcomed the Standing Committee and participants to the web meeting. After the co-chairs provided welcoming remarks, Dr. Matthew Pickering, NQF managing director, informed the Standing Committee that the Centers for Medicare & Medicaid Services (CMS) contract to serve as the consensus-based entity is set to end on March 26 of this year. CMS recently completed a competitive process to award the next phase of work and announced its award decision: NQF was not awarded the contract, so its work will conclude on March 26, 2023. Dr. Pickering further mentioned that NQF is working with CMS and the successor contractor in the weeks ahead to make a smooth transition, which will include further communication with this Standing Committee and other NQF Committee volunteers. However, Dr. Pickering underscored that this does not change the Standing Committee's focus for the measure evaluation meeting, and NQF looks forward to working with the Committee to review the fall 2022 measures.

NQF staff reviewed the meeting objectives. Following this review, the Standing Committee members each introduced themselves and disclosed any conflicts of interest. Five Standing Committee members disclosed a conflict with NQF #3722 and NQF #3725, which led to their recusal from the discussion of those measures. Those five Standing Committee members were recused from the discussion of NQF #3722 and NQF #3725 due to their collaboration with the measure developer on the development of those measures. Additionally, Gabrielle Kyle-Lion, NQF manager, reviewed the Consensus Development Process (CDP) and the measure evaluation criteria.

Some Standing Committee members were unable to attend the entire meeting due to early departures and late arrivals. The vote totals reflect members present and eligible to vote. A quorum of 15 members for NQF #3719 and a quorum of 12 members for both NQF #3722 and NQF #3725 was met and maintained for the entirety of the meeting. Voting results are provided below.

Measure Evaluation

During the meeting, the Renal Standing Committee evaluated three new measures for endorsement consideration. Prior to the review of the measures, Dr. Pickering noted that for the fall 2022 cycle, measures were reviewed by the Scientific Methods Panel (SMP) if they were deemed as complex (i.e., outcome, cost, composite, or instrument-based measures) and/or if they included testing methods that are not commonly used. For the renal measures under review, two of the three measures, NQF #3722 and NQF #3725, were evaluated by the SMP.

A measure is recommended for endorsement by the Standing Committee when greater than 60 percent of eligible voting members select a passing vote option (i.e., Pass, High and Moderate, or Yes) on all must-pass criteria and overall suitability for endorsement. A measure is not recommended for

endorsement when less than 40 percent of voting members select a passing vote option on any must-pass criterion or overall suitability for endorsement. If a measure does not pass a must-pass criterion, voting during the measure evaluation meeting will cease. The Standing Committee will not re-vote on the measures during the post-comment meeting unless the Standing Committee decides to reconsider the measure(s) based on submitted comments or a formal reconsideration request from the developer. The Standing Committee has not reached consensus on the measure if between 40 and 60 percent of eligible voting members select a passing vote option on any must-pass criterion or overall suitability for endorsement. The Standing Committee will re-vote on criteria for which it did not reach consensus and potentially on overall suitability for endorsement during the post-comment web meeting.

Voting Legend:

- *Evidence (Outcome Measures) and Use:* Pass/No Pass
- *Accepting the SMP Rating and Overall Suitability for Endorsement*: Yes/No
- *All Other Criterion:* H – High; M – Moderate; L – Low; I – Insufficient; NA – Not Applicable
- *Maintenance Criteria for Which the Standing Committee Decided Additional Discussion/Vote Was Not Needed (Evidence, Reliability, Validity only):* Accepted Previous Evaluation

NQF #3719 Prevalent Standardized Waitlist Ratio (PSWR) (Centers for Medicare & Medicaid Services [CMS]/University of Michigan-Kidney Epidemiology Cost Center [UM-KECC])

Description: The Prevalent Standardized Waitlist Ratio (PSWR) measure tracks the number of prevalent dialysis patients in a practitioner (inclusive of physicians and advanced practice providers) group who are under the age of 75 and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant. For each practitioner group, PSWR is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. The PSWR uses the expected waitlist events calculated from a Cox model, adjusted for patient age, incident and prevalent comorbidities, previous waitlisting and transplant, dual eligibility, Area Deprivation Index (ADI), and transplant center characteristics; **Measure Type**: Outcome; **Level of Analysis**: Clinician: Group/Practice; **Setting of Care**: Outpatient Services; **Data Source**: Claims; Registry Data

Measure Steward/Developer Representatives at the Meeting

- Dr. Vahakn Shahinian

Standing Committee Votes

- **Evidence**: Total Votes-18; Pass-17; No Pass-1 (17/18 – 94.4%, Pass)
- **Performance Gap**: Total Votes-18; H-2; M-14; L-2; I-0 (16/18 – 88.9%, Pass)
- **Reliability**: Total Votes-18; H-0; M-14; L-3; I-1 (14/18 – 77.8%, Pass)
- **Validity**: Total Votes-17; H-1; M-4; L-11; I-1 (5/17 – 29.4%, No Pass)
- **Feasibility**: Vote Not Taken
- **Use**: Vote Not Taken
- **Usability**: Vote Not Taken
- **Standing Committee Recommendation for Endorsement:** Vote Not Taken

The Standing Committee did not vote on overall suitability for endorsement because the measure failed to pass on validity—a must-pass criterion.

This clinician group/practice-level measure was newly submitted for endorsement. This measure is not yet implemented in a quality or accountability program. The developer stated that the measure may be considered for use in a public-reporting/payment program in the future.

Dr. Pickering summarized the one comment received for this measure prior to the measure evaluation meeting. The comment did not express support for the measure. The commenter disagreed with this measure being attributed to physicians because the decision to waitlist a patient is made by transplant centers. The commenter also asserted that variation in transplant center waitlisting practices must be better accounted for in order for the measure to be valid. Lastly, the commenter raised concern with the reliability statistics because they were not stratified by facility size; therefore, it is not possible to discern reliability for smaller units. The Standing Committee considered these comments in its evaluation of the measure.

While the Standing Committee agreed that the developer presented evidence highlighting the relationship between a provider's actions and waitlisting, the conversation focused on the possible unintended harm due to the measure's use. Specifically, the Standing Committee was concerned that incentivizing providers to waitlist patients could overburden already overloaded transplant centers and delay indicated transplant candidates from being assessed by the transplant center. Additional concern was raised that patients who are either unwilling or unable to receive a transplant will get waitlisted. Dr. Pickering clarified for the Standing Committee that concerns regarding unintended harm due to the measure's use are applicable during the evaluation of the use and usability criteria rather than the evaluation of the evidence. The developer further clarified that most of the empirical evidence suggests that patients who could benefit from a transplant are not being added to the waitlist and that there is no evidence to suggest that the posed unintended consequences are commonplace. The Standing Committee did not raise any additional concerns or questions and passed the measure on evidence.

Regarding performance gap, the Standing Committee asked the developer to clarify how they should interpret the information provided in the submission in relation to gap and disparities. Particularly, the developer calculated PSWR performance among different strata of race, ethnicity, and sex, and the mean values for each of the strata are different than the median values. The developer clarified that the medians show the most precise picture of gap and disparities. The Standing Committee noted that with respect to the medians, it appears that the PSWR for people who are Black, Native American /Alaska Native, Asian/Pacific Islander, and those who identified as "other" was lower than for people who are White. Additionally, Hispanics and males had a lower PSWR than non-Hispanics and females. The Standing Committee recognized that a gap in care and disparities do exist and passed the measure on performance gap.

During its discussion on reliability, the Standing Committee asked the developer to clarify how the measure is calculated, particularly if a patient were to move between provider groups but is waitlisted early on. The developer noted that the outcome is a one-time event; therefore, if a patient is waitlisted by their first provider group and then subsequently moves to a new provider group, they would not be counted in that subsequent group's denominator because the first group has already waitlisted them. The Standing Committee asked the developer to clarify the exclusion of 11 patients or less and specifically whether this applies to the 11 patients on dialysis and assigned to the practice or to the 11 waitlisted patients. The developer noted that the exclusion is for 11 total dialysis patients in the denominator. The Standing Committee also asked the developer to clarify whether preemptively waitlisted patients are included in the measure. The developer noted that people who are preemptively waitlisted are not included in this measure's calculation. Lastly, the Standing Committee asked whether the developer looked at reliability for smaller practices and how many groups are smaller in size. The

developer noted that they did not look at smaller practices but that they would expect the reliability to be lower. The developer further noted that the exclusion of less than 11 patients or less than two waitlisting events is to address the concern of reliability for smaller clinician groups. The Standing Committee passed the measure on reliability. –

Moving to validity, the Standing Committee posed several questions to the developer regarding concerns around exclusions, the nonsignificant association with mortality, risk adjustment, and the possibility of practices with high waitlisting rates not performing well on this measure. The Standing Committee noted the exclusions were insufficient, given preemptively waitlisted patients are excluded, while pediatric patients weighing less than 10 kilograms and patients who choose not to be waitlisted are not excluded. The two patient advocates on the Standing Committee were particularly concerned by the lack of patient choice, and even physician choice, regarding this measure. The developer noted that in practice, there are difficulties in attributing the correct dialysis facility for preemptive waitlisting and that patient choice is difficult to capture accurately. Further, the developer reiterated that the focus of this measure is on transplants and the waitlisting that occurs after dialysis initiation. Regarding the pediatric patient exclusion, the developer noted that its approach was to exclude situations that can cause imbalances across groups. The Standing Committee noted that while these numbers may appear to be small nationally, they would be significant for pediatric centers. Additionally, the exclusion of less than 11 patients may suppress some of these centers, but there are larger pediatric centers that may not be excluded. As for the nonsignificant associations with mortality in the validity testing, the developer noted that it can be challenging to show a clearly demonstrable effect on mortality because it is inclusive of many factors. However, the developer did find a numerical trend that is consistent with what they hoped to see.

Regarding risk adjustment, the developer clarified that transplant center mortality and transplant rates were chosen as characteristics to account for variation in the model because they are proxies for the aggressiveness with which centers are willing to waitlist patients, particularly sicker ones; regional organ availability; and how aggressively they try to find living donors or convert patients to transplants. As for the possibility of practices with high waitlisting rates not performing well on this measure, the developer noted that the measure adjusts for comorbidities on an ongoing basis, along with other adjustments, to continually update who is expected to be rapidly waitlisted in the denominator as the measurement period continues. The Standing Committee asked whether the developer had performed any analyses on how high-performing groups performed on this measure to ensure that the developer's rationale is indeed how this scenario works. The developer replied that they had not.

The Standing Committee did not pass the measure on validity—a must-pass criterion; therefore, it did not discuss or vote on any proceeding criteria.

NQF #3722 Home Dialysis Rate (Kidney Care Quality Alliance)

Description: Percent of all dialysis patient-months in the measurement year in which the patient was dialyzing via a home dialysis modality; **Measure Type**: Process; **Level of Analysis**: Facility; Other; **Setting of Care**: Ambulatory Care; Home Care; Outpatient Services; Post-Acute Care; **Data Source**: Electronic Health Data; Electronic Health Records

Measure Steward/Developer Representatives at the Meeting

- Kathleen Lester, JD, MPH
- Lisa McGonigal, MD, MPH
- Dr. Dave Gilbertson

- Dr. Suying Li

Standing Committee Votes

- **Evidence**: Total Votes-12; H-0; M-3; L-7; I-2 (3/12 – 25.0%, No Pass)
- **Performance Gap**: Vote Not Taken
- **Reliability**: Vote Not Taken
- **Validity**: Vote Not Taken
- **Feasibility**: Vote Not Taken
- **Use**: Vote Not Taken
- **Usability**: Vote Not Taken
- **Standing Committee Recommendation for Endorsement:** Vote Not Taken

The Standing Committee did not vote on overall endorsement because the measure failed to pass on evidence—a must-pass criterion.

This Hospital Referral Region (HRR) and facility-level measure was newly submitted for endorsement. It is not yet implemented in a quality or accountability program. However, the developer stated that they plan to engage the Center for Medicare & Medicaid Innovation (CMMI) to add the measure to the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Payment Model and possibly to the Kidney Care Choices (KCC) Models. The developer also plans to submit this measure to the Measures Under Consideration (MUC) list for adoption into the ESRD program. In addition, the developer stated that they may request CMS to propose the measure for adoption into the ESRD proposed rule.

The Standing Committee's lead discussant noted that one comment was received for this measure prior to the measure evaluation meeting. The commenter expressed support for NQF #3722, noting that home modalities lead to favorable clinical and patient-reported outcomes. The commenter further stated that home modalities are underutilized and that increasing utilization is a major objective of the ETC Payment Model. The Standing Committee considered the comment in its evaluation of the measure.

The Standing Committee recognized the measure's intent to incentivize home modalities for all clinically appropriate patients. The Standing Committee reviewed the developer's logic model, which highlights potential outcomes of increased home dialysis, such as the reduced risk of cardiovascular disease, mortality, hospitalization, cost, and increased quality of life. During the Standing Committee's discussion on evidence, the Standing Committee focused on determining whether there is strong enough evidence that home modalities provide better outcomes than in-center dialysis treatments. The Standing Committee did recognize increasing home modalities can lead to reduced costs. However, several Standing Committee members expressed that some patient subgroups tend to have varying health and quality-of-life outcomes due to other confounding factors. Specifically, patients who choose to go home and who report a higher quality of life are generally healthier, more motivated, and tend to have greater financial and social resources, as well as a more conducive home environment for home modalities. For this reason, Standing Committee members expressed concern regarding the denominator exclusions and specified that the denominator should not include all patients.

The Standing Committee also pointed out that home dialysis outcomes may be worse than in-center outcomes for some patient subgroups, such as diabetic patients. One member highlighted a post hoc analysis that resulted in worse mortality outcomes among patients at home versus in-center. Overall, members of the Standing Committee recognized that the observational studies presented by the developer suggest that there are some advantages to home therapies, but this is likely a reflection of the composition of those patients who choose to go home. The developer mentioned that the evidentiary standard for measures regarding ESRD cannot be prospective trials. Specifically, the developer stated it

would be unethical to suggest that a home dialysis measure cannot exist without having a randomized control trial. However, one Standing Committee member noted that there are dialysis studies that are prospective randomized trials and that the current observational studies have significant vulnerabilities.

The Standing Committee expressed uncertainty about the developer's use of a nine-member panel to systematically assess the measure's importance. The developer emphasized in their response that patient groups as well as clinical experts from accredited nephrology associations and dialysis facilities drove the development of this measure. Ultimately, the Standing Committee stated that the true benefits of home dialysis over in-center dialysis are not currently demonstrated in the literature and that there is no empirical evidence to suggest the benefits of home modalities lead to better outcomes that outweigh undesirable effects for all patients.

The Standing Committee did not pass the measure on evidence—a must-pass criterion; therefore, the Standing Committee did not discuss or vote on any proceeding criteria.

NQF #3725 Home Dialysis Retention (Kidney Care Quality Alliance)

Description: Percent of all new home dialysis patients in the measurement year for whom greater than or equal to 90 consecutive days of home dialysis was achieved; **Measure Type**: Outcome: Intermediate Clinical Outcome; **Level of Analysis**: Facility; Other; **Setting of Care**: Ambulatory Care; Home Care; Outpatient Services; Post-Acute Care; **Data Source**: Electronic Health Data; Electronic Health Records

Measure Steward/Developer Representatives at the Meeting

- Kathleen Lester, JD, MPH
- Lisa McGonigal, MD, MPH
- Dr. Dave Gilbertson
- Dr. Suying Li

Standing Committee Votes

- **Evidence**: Total Votes-13; H-0; M-4; L-7; I-2 (4/13 – 30.7%, No Pass)
- **Performance Gap**: Vote Not Taken
- **Reliability:** Vote Not Taken
- **Validity:** Vote Not Taken
- **Feasibility:** Vote Not Taken
- **Use:** Vote Not Taken
- **Usability:** Vote Not Taken
- **Standing Committee Recommendation for Endorsement:** Vote Not Taken

The Standing Committee did not vote on overall endorsement because the measure failed to pass on evidence—a must-pass criterion. This HRR and facility-level measure was newly submitted for endorsement. It is not yet implemented in a quality or accountability program, but the developer plans to engage CMS and, in particular, CMMI to add the measure to the ETC Model and potentially the KCC Models. The developer also plans to submit this measure to the MUC list for adoption into the ESRD program. In addition to doing so, the developer stated that they may request CMS to propose the measure for adoption into the ESRD proposed rules.

The Standing Committee's lead discussant summarized the one comment received for this measure prior to the measure evaluation meeting. The comment expressed support for NQF #3725 and was submitted by the developer. The comment stated that in the absence of appropriate safeguards and a sufficiently robust infrastructure to support the anticipated rapid increase in home modalities use, there

is concern among patient and advocate stakeholders that the current unilateral focus on home growth will certainly lead to increased technique failure rates, may subject many patients to a treatment modality for which they have not received adequate education or training, and may even inadvertently infringe on patient choice. The developer added that the retention measure will allow providers to more readily assess the success of their efforts to create a sustainable home dialysis program through appropriate patient education, preparation, and support and apply targeted quality improvement interventions when and where needed. The Standing Committee considered the comment in its evaluation of the measure.

The Standing Committee recognized the measure's intent to serve as a guardrail to prevent patients from being inappropriately waitlisted for home dialysis. The Standing Committee reviewed the developer's logic model, which asserts that implementation of the measure will incentivize facilities to implement process interventions to improve home dialysis retention among patients who have selected and commenced a home modality. During its discussion on evidence, the Standing Committee noted that the evidence provided was based on empirical studies and opinions from a technical expert panel (TEP) convened by the developer. However, the developer noted in their submission that to date, there are no relevant clinical practice guidelines, recommendations, systematic reviews, or formal randomized controlled studies addressing uptake in home dialysis modalities. Further, the Standing Committee observed that much of the evidence for NQF #3725 was similar to the evidence provided for NQF #3722. The Standing Committee stated that the measure could reduce costs for patients who choose home dialysis. However, it disagreed with the developer that there was evidence to support improved outcomes for home dialysis over in-center treatment regarding cardiovascular disease, mortality, or hospitalizations, as was noted in the conversation for NQF #3722.

The Standing Committee further expressed concern that the measure may not be able to accurately identify whether people who drop out of home dialysis prior to 90 days do so due to the guardrail functionality described by the developer or biological reasons, such as infection or decrease in renal function. The developer noted that they had to practically consider what is achievable and can be reported. The developer also emphasized that benchmarks built into programs will be able to identify patients who are unable to stay on home dialysis for a clinical reason.

The Standing Committee expressed concern regarding the evidence provided to justify the 90-day time period for the measure. Specifically, the evidence submitted does not point to 90 days as a definitive time frame for success on home dialysis. The developer noted that 90 days was chosen based on the consensus reached in their TEP. Additionally, the Standing Committee raised the potential for unintended consequences, such as limiting access to therapy, due to the 90-day time period. Specifically, access to therapy could be limited because providers may be disincentivized from having patients try home therapy when they are unconvinced that the patient could maintain home dialysis for the full 90-day period. A Standing Committee member did note that the measure has an already built-in 30-day escape mechanism, where patients are not counted if they stop home dialysis before the 30-day mark to try and address this concern.

The Standing Committee did not pass the measure on evidence—a must-pass criterion; therefore, it did not discuss or vote on any proceeding criteria.

Public Comment

Dr. Pickering opened the lines for NQF member and public comments. No comments were provided at this time or during the measure evaluation meeting.

Next Steps

Nicholas Barone, NQF analyst, provided an overview of the next steps. NQF will begin drafting the meeting summary of the Standing Committee's deliberations. Dr. Pickering iterated the earlier statement about the future communications to NQF stakeholders about the transition of the endorsement and maintenance work to the new successor. Dr. Pickering thanked the Standing Committee for its time, engagement, and participation in this work and adjourned the call.