Primary Care and Chronic Illness Standing Committee—Spring 2023 Measure Evaluation Meeting Summary

Battelle, a consensus-based entity (CBE), convened the Primary Care and Chronic Illness (PCCI) standing committee for a web meeting on July 31, 2023, to evaluate six measures for the Spring 2023 cycle. As these Spring 2023 measures began their endorsement process with an Intent to Submit under the prior CBE, the National Quality Forum (NQF), they were reviewed using the NQF process and criteria for continuity of review.

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

Matthew Pickering, endorsement and maintenance technical lead, welcomed the standing committee and participants to the meeting. After the co-chairs provided welcoming remarks, deputy director, Brenna Rabel also provided welcoming remarks and thanked the committee for their continued engagement. Dr. Pickering reviewed the meeting objectives and conducted roll call. The standing committee members each introduced themselves and disclosed any conflicts of interest. One standing committee member, Adam Thompson, disclosed a conflict with CBE #3210e, 3752e, and 3755e because he served on a technical expert panel (TEP) for these three measures, which led to his recusal from the discussion and voting of those measures. One standing committee member, Lorien Dalrymple, was recused from CBE #3742 due to her involvement on a patient-reported outcome TEP that provided guidance on the conceptual framework for the measure.

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 12 was met and maintained for the entirety of the meeting. Voting results are provided below.

Measure Evaluation

Isaac Sakyi, social scientist, reviewed the measure evaluation process and the measure evaluation criteria. During the meeting, the PCCI standing committee evaluated six measures (one maintenance and five new) for endorsement consideration.

A measure is recommended for endorsement by the standing committee when greater than 60 percent of eligible voting members select a passing vote option (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 measure during the post-comment meeting unless the standing committee decides to reconsider the measure 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 that did not reach consensus and potentially on overall suitability for endorsement during the post-comment web meeting.

The standing committee was not able to discuss related and competing measures during the meeting due to time constraints, and that discussion will occur during the post-comment meeting.

Voting Legend:

- *Evidence (Outcome Measures) and Use:* Pass/No Pass
- *Overall Suitability for Endorsement:* Yes/No
- *All Other Criteria:* 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

CBE #3210e HIV Viral Suppression (Health Resources and Services Administration [HRSA] - HIV/AIDS Bureau)

Description: Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first three months of the measurement period, with an eligible encounter in the first eight months of the measurement period, who have a last HIV viral load test of less than 200 copies/mL during the measurement period. **Measure Type:** Outcome; **Level of Analysis:** Clinician: Individual **Setting of Care:** Outpatient Services; **Data Source:** Electronic Health.

Measure Steward/Developer Representatives at the Meeting

- Keri Calkins
- Marlene Matosky

Standing Committee Votes

- **Evidence:** Total Votes-15; Pass-15; No Pass-0 (15/15 – 100%, Pass).
- **Performance Gap:** Total Votes-15; H-1; M-14; L-0; I-0 (15/15 – 100%, Pass).
- **Reliability:** Total Votes-15; H-1; M-14; L-0; I-0 (15/15 – 100%, Pass).
- **Validity:** Total Votes-15; H-0; M-15; L-0; I-0 (15/15 – 100%, Pass).
- **Feasibility:** Total Votes-15; H-1; M-13; L-1; I-0 (14/15 – 93%, Pass).
- **Use:** Total Votes-15; Pass-14; No Pass-1 (14/15 – 93%, Pass).
- **Usability:** Total Votes-15; H-0; M-4; L-1; I-10 (4/15 – 27%, No Pass).
- **Standing Committee Recommendation for Endorsement:** Total Votes-15; Yes-15; No-0 (Yes/Total Votes – 100%, Pass).

The standing committee recommended this electronic clinical quality measure (eCQM) for continued endorsement. This clinician-level measure was originally endorsed in 2017. This measure is not currently implemented in a Federal program, but a Merit-based Incentive Payment System (MIPS) clinical quality measure (CQM) version of the measure is currently in use, and HRSA submitted this measure for use as a clinician-level measure to the Centers for Medicare & Medicaid Services (CMS) MIPS program starting in 2024.

Prior to the meeting this measure received one public comment stressing the importance of tracking viral suppression along with broader wellness-related quality measures in order to get a holistic view of quality care for those living with HIV. The committee considered this comment in its evaluation of the measure.

Standing committee members agreed there is considerable evidence that HIV viral load is linked with several clinically relevant outcomes, including disease progression and incidence of opportunistic infections. No member reported knowing of new studies that contradicted the evidence base. The standing committee agreed that the measure was important and passed the measure on the evidence criterion. Moving to performance gap, the committee agreed that the performance has improved since 2017. However, the committee noted there are disparities that remain and an overall gap persists among racial/ethnic minority populations. The committee therefore passed the measure on performance gap.

The standing committee reviewed the updated measure specifications and reliability testing, which was conducted at the accountable entity level using electronic health record (EHR) data. The committee did not raise any concerns and passed the measure on reliability. For validity, the standing committee reviewed submitted testing data, and the threats to validity were discussed. Committee members did not express significant concerns related to validity during the discussion and voted to pass the measure on validity.

The standing committee had a concern with respect to the feasibility of the measure. The committee noted that EHR constraints may have implications on the ability to capture the diagnosis date consistently across study sites. The developer shared how this information was captured via unstructured data fields and how clinical sites plan to address this limitation through workflow changes in the future. The committee did not have any additional concerns and passed the measure on feasibility.

Moving to use and usability, the committee recognized that the “Use” criterion is a must-pass criterion for maintenance measures and that the measure is currently not in use, as the developer indicated in its submission. During the meeting, the developer disclosed that this measure was selected for inclusion in MIPS for 2024 and is being considered for an infectious disease value pathway. The committee had no further concerns and passed the measure on use. For usability, since the measure has not been used, the committee acknowledged that data on improvement over time were not available, including any assessment of the potential harms as a result of the measure’s use. Therefore, the committee did not pass the measure on usability.

Overall, the committee voted to recommend the measure for continued endorsement.

CBE #3752e HIV Annual Retention in Care (HRSA - HIV/AIDS Bureau)

Description: Percentage of patients, regardless of age, with a diagnosis of HIV who had at least two eligible encounters or at least one eligible encounter and one HIV viral load test that were at least 90 days apart within the measurement period. **Measure Type:** Process; **Level of Analysis:** Clinician: Individual; **Setting of Care:** Outpatient Services; **Data Source:** Electronic Health Records.

Measure Steward/Developer Representatives at the Meeting

- Keri Calkins
- Marlene Matosky

Standing Committee Votes

- **Evidence:** Total Votes-15; H-1; M-13; L-1; I-0 (14/15 – 93%, Pass).

- **Performance Gap:** Total Votes-15; H-1; M-9; L-4; I-1(10/15 – 67%, Pass).
- **Reliability:** Total Votes-15; H-8; M-5; L-2; I-0 (13/15 – 87%, Pass).
- **Validity:** Total Votes-14; H-0; M-12; L-1; I-1 (12/14 – 86%, Pass).
- **Feasibility:** Total Votes-14; H-1; M-13; L-0; I-0 (14/14 – 100%, Pass).
- **Use:** Total Votes-14; Pass-14; No Pass-0 (14/14 – 100%, Pass).
- **Usability:** Total Votes-14; H-1; M-9; L-4; I-0 (10/14 – 71%, Pass).
- **Standing Committee Recommendation for Endorsement:** Total Votes-14; Yes-13; No-1 (13/14 – 93%, Pass).

The standing committee recommended this eCQM for initial endorsement. This clinician-level measure was newly submitted for endorsement. HRSA submitted this measure for use in the CMS MIPS program.

Prior to the meeting this measure received one public comment raising concern with duplication of measures, as this measure is similar to a group of measures called, “HIV Medical Visit Frequency,” developed by the HIV AIDS Bureau of HRSA. The committee considered this comment in its evaluation of the measure.

The standing committee reviewed the evidence submitted, which supported routine monitoring of retention in care for HIV treatment, the linkages between poor care retention and lower rates of anti-retroviral therapy adherence, delayed viral suppression, and increased mortality risk.

One committee member noted that most of the evidence was from 2011 or earlier. Other committee members agreed but recognized that the developer provided a more recent guideline from 2019 in the submission that strengthened the prior evidence. The committee did not raise any additional concerns and voted to pass the measure on evidence. Moving to performance gap, the standing committee discussed whether the data are generalizable, as the measure submission used data from patients from the Ryan White HIV/AIDS program clinical studies. Committee members noted that these clinical sites are often held to higher performance standards and oversight due to federal funding, which could potentially skew the performance rates. The developer responded to the committee’s concern by noting the recruiting burden involved in this type of research and shared that it had an existing relationship with Ryan White sites, which made engagement in measure testing more feasible. Additionally, the developer emphasized that stakeholders across all sites, including those not participating in the Ryan White program, view HIV annual retention in care as a priority outcome for the community. Based on these discussions, committee members voted to pass this measure on performance gap.

In reviewing scientific acceptability (i.e., reliability and validity), the committee raised no concerns with reliability. Regarding validity, the committee did not raise any major concerns with validity testing but did draw attention to accuracy issues of two data elements as they were not available at one or more of the test sites, “Encounter Performed: Home Healthcare Services" and "Encounter, Performed: Outpatient Consultation." However, the devleoper indicated that neither is required to calculate the measure. The committee therefore passed the measure on both reliability and validity.

The ability of EHRs to routinely capture the data required for this measure was discussed as part of feasibility. The committee discussed feasibility implications of the data elements specified in the measure, resolving that for sites lacking structured data fields, unstructured methods could be used to calculate the measure as specified. Moving to a vote, the committee passed the measure on feasibility.

The committee acknowledged the planned use of the measure as part of MIPS in 2024 and passed the measure on the use criterion. Regarding usability, some committee members questioned how results of this metric might be used to effectively increase adherence to best practice. Other committee members commented that this measure may be used in team-based care across specialty areas for medication adherence and care and that having a measure like this can benefit underserved areas without Ryan White-affiliated clinics.

Overall, the standing committee voted to recommend the measure for initial endorsement.

CBE #3755e STI Testing for People with HIV (HRSA - HIV/AIDS Bureau)

Description: Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the measurement period; **Measure Type:** Process; **Level of Analysis:** Clinician: Individual; **Setting of Care:** Outpatient Services; **Data Source:** Electronic Health Records.

Measure Steward/Developer Representatives at the Meeting

- Keri Calkins
- Marlene Matosky

Standing Committee Votes

- **Evidence:** Total Votes-15; H-0; M-7; L-7; I-1 (7/15 – 47%, Consensus Not Reached).
- **Performance Gap:** Total Votes-15; H-0; M-12; L-3; I-0 (12/15 – 80%, Pass).
- **Reliability:** Total Votes-15; H-9; M-4; L-1; I-1 (13/15 – 87%, Pass).
- **Validity:** Total Votes-15; H-0; M-7; L-8; I-0 (7/15 – 47%, Consensus Not Reached).
- **Feasibility:** Total Votes-15; H-0; M-15; L-0; I-0 (15/15 – 100%, Pass).
- **Use:** Total Votes-15; Pass-12; No Pass-3 (12/15 – 80%, Pass).
- **Usability:** Total Votes-15; H-0; M-9; L-6; I-0 (9/15 – 60%, Consensus Not Reached).
- **Standing Committee Recommendation for Endorsement:** Not taken.

The standing committee did not vote on the recommendation for endorsement during the meeting because the committee did not reach consensus on evidence and validity, which are must-pass criteria. The committee will re-vote on the measure during the post-comment web meeting.

This clinician-level eCQM was newly submitted for endorsement. HRSA submitted this measure for use as a clinician-level measure in the CMS MIPS program, and it will be implemented in 2024. Prior to the meeting, this measure received two public comments. The first emphasized that the measure is important and relevant as sexually transmitted infections (STIs) are rising. The second comment raised a similar redundancy concern as CBE #3752e, noting that this measure is similar to other measures developed by the HIV/AIDS Bureau of HRSA. The committee considered these comments in its evaluation of the measure.

The Standing Committee reviewed the evidence provided regarding STI testing for syphilis, gonorrhea, and chlamydia among persons with HIV. The committee questions why all three conditions were included within a single measure, which the developer explained was at the request of CMS. The developer also noted that this measure will replace CBE #0409, which is the CQM version also stewarded by HRSA. The committee noted that the evidence in support of inclusion of syphilis in the measure was the strongest but that there was suitable evidence to

support inclusion of gonorrhea and chlamydia in the measure as well. There was some concern among committee members that this measure requires testing for all three conditions, with no option for providers to achieve a score if they tested for only one or two STIs. Some committee members noted that the evidence seems to suggest that testing should be conducted annually or even more frequently for certain individuals. The measure does not seem to have the ability to differentiate between those two points, especially for sexually active and non-sexually active persons, as the measure only indicates if the tests have been once in the measurement period. In response to this concern, the developer emphasized the positive impact of STI testing on health outcomes. Ultimately, the standing committee did not reach consensus on evidence.

Moving to performance gap, the committee did not raise any major concerns, noting that an overall gap exists and that mean rates of STI testing were higher in those under 50 years old, but no significant differences by race or ethnicity. The committee voted to pass the measure on performance gap.

Regarding reliability, the committee did not have any major concerns and passed the measure on reliability. For validity, although the developer demonstrated sufficient data element validity and construct validity, several members voiced concerns that the validity testing conducted did not explore the correlation between annual testing and reduced infection rates or better patient outcomes. As a result, the committee did not reach consensus on validity.

There was minimal discussion around feasibility, with committee members voting to pass feasibility criteria based on the prior discussion for CBE #3752e. Regarding the use criterion, committee members recognized the measure's planned use in MIPS in 2024 and passed the measure on use. For usability, some standing committee members raised a concern that introducing mandatory or routine STI testing for persons with HIV may unintentionally perpetuate stigma around HIV and increase discrimination against those living with the virus. People with HIV might feel singled out and face further marginalization due to additional testing requirements. However, others commented that by integrating STI testing into the regular care of persons with HIV, health care providers can address multiple health concerns simultaneously, leading to more comprehensive and holistic care. Ultimately, the committee did not reach consensus on usability.

A vote on overall suitability was not taken since the committee did not reach consensus on two must-pass criteria, evidence and validity.

CBE #3742 ESRD Dialysis Patient Life Goals Survey (PaLS) (CMS/University of Michigan Kidney Epidemiology and Cost Center)

Description: The PaLS is a patient self-report survey that includes eight items related to dialysis facility care team discussions about patient life goals. Six of the items are Likert-type items that are used to generate a "quality of facility care team discussion" score (described below). The remaining two items on the PaLS are checklist items: (1) a list of patient-reported life goals; and (2) a patient-reported list of dialysis care team members that the patient reports have talked with them about their life goals. These items are not scored. Instead, these items serve to provide contextual information for both the patient and the facility to guide care team discussions. **Measure Type:** Process; **Level of Analysis:** US Chronic Dialysis Population (patient-level); **Setting of Care:** Outpatient Services; **Data Source:** Claims, Instrument-Based Data, Registry Data.

Measure Steward/Developer Representatives at the Meeting

- Claudia Dahlreus

Standing Committee Votes

- **Evidence:** Total Votes-16; H-0; M-2; L-13; I-1 (2/16 – 13%, No Pass).
- **Performance Gap:** Not taken
- **Reliability:** Not taken
- **Validity:** Not taken
- **Feasibility:** Not taken
- **Use:** Not taken
- **Usability:** Not taken
- **Standing Committee Recommendation for Endorsement:** Not taken

The standing committee did not recommend this measure for initial endorsement as it did not pass on evidence—a must-pass criterion.

This patient-level measure was newly submitted for initial endorsement. This measure is not currently in use, but the developer shared plans for its use, including potential applications for the measure in the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) or the Dialysis Facility Care Compare program on Medicare.gov.

Prior to the meeting, this measure received 18 public comments. One comment was supportive, recognizing the importance of patient-centered care in ESRD quality and promoting the use of shared decision-making. The remaining 17 comments raised concerns with the measure due to lack of appropriate testing, survey fatigue for patients with ESRD, and administrative burden to administer the survey. Additionally, comments submitted by ESRD patients drew concern with the appropriateness for surveying life goals without resulting action to achieve those life goals and that survival is the life goal. The committee considered these comments in its evaluation of the measure.

In its review of the evidence provided for this measure, committee members shared concerns that the evidence provided did not show a clear patient desire for this type of measurement and there is a lack of alignment with patient-preferred outcomes, as seen in several public comments. Ultimately, 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 subsequent criteria.

The committee provided recommendations for the developer regarding the evidence needed to support the measure. The committee suggested that the developer consider ways to clearly show that ESRD patients value this type of outcome. In addition, there needs to be more evidence to clearly indicate how this measure will improve patient outcomes.

CBE #3753 Delay in Progression of Chronic Kidney Disease (CKD) Measure (CMS/Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation [Yale CORE])

Description: Delay in Progression of CKD Measure is an outcome measure to assess how well providers delay progression from Stage 4 CKD to end-stage renal disease (ESRD) requiring chronic dialysis. The measure includes adult Medicare Fee-For-Service (FFS) beneficiaries with

Stage 4 CKD. The measure outcome captures beneficiaries with Stage 4 CKD who progress to ESRD and require chronic dialysis. This measure is for nephrology practices (also referred to as "providers" in this submission) who care for patients with Stage 4 CKD.; **Measure Type:** Outcome; **Level of Analysis:** Clinician: Group/Practice; **Setting of Care:** Ambulatory care; **Data Source:** Claims; Other (Beneficiary Enrollment data including the hospice enrollment, ESRD or dialysis enrollment).

Measure Steward/Developer Representatives at the Meeting

- Kyle Bagshaw

Standing Committee Votes

- **Evidence:** Total Votes-16; Pass-0; No Pass-16 (0/16 – 0%, No Pass)
- **Performance Gap:** Not taken
- **Reliability:** Not taken
- **Validity:** Not taken
- **Feasibility:** Not taken
- **Use:** Not taken
- **Usability:** Not taken
- **Standing Committee Recommendation for Endorsement:** Not taken

The standing committee did not recommend this measure for initial endorsement as it did not pass on evidence—a must-pass criterion.

This clinician group/practice-level measure was newly submitted for initial endorsement. This measure is not currently in use, but the developer shared plans for its use in the voluntary Kidney Care Choices model.

Prior to the meeting, this measure received seven public comments, which raised concern regarding staffing shortages in dialysis facilities and testing and specification concerns, including risk adjustment and exclusions. One comment noted that this measure may limit a provider's ability to make meaningful change in the trajectory of the patient's illness. The committee considered these comments in its evaluation of the measure.

During the evidence discussion, committee members commented on the age of some of the studies provided, noting that the developer had evidently overlooked more recent, relevant studies. Therefore, the committee questioned the suitability of some of the older studies cited, with some committee members noting that the evidence provided refers to certain interventions that are not consistent with standard of care, such as erythropoiesis-stimulating agents. A committee member further noted that the evidence that angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers delay progression of kidney disease show only a very modest effect, and it has not been shown in empiric trials that initiating this therapy significantly delays progression. In contrast, recent studies not cited by developers show a much more powerful effect to delay or stop progression with other medications, such as SGLT-2 inhibitors, GLP1 agonists, and nonsteroidal RAAS inhibitors. The patient representative on the committee living with diabetes and CKD raised concern with the exclusion of diabetes patients with CKD and the lack of evidence supporting this exclusion. Moving to a vote, 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.

The committee provided recommendations for the developer, which included providing more recent evidence and evidence that better reflects how special populations living with CKD, like those patients with diabetes, are reflected in the measure. The committee also provided feedback with respect to the measure's validity, noting that patients qualify for inclusion in the measure when their estimated glomerular filtration rate (eGFR) is between 15 and 30 ml/min. Time to dialysis start is directly related to initial eGFR, so there is predictably large variation dependent not on the quality of care, but on eGFR at enrollment. The developer may want to consider potential risk adjustment of eGFR, as noted by members of a developer-convened technical expert panel, or to explore a GFR-based measure.

CBE #3754 Risk Standardized Mortality Ratio for Late-Stage Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD) (CMS/Yale CORE)

Description: The Risk Standardized Mortality Ratio for Late-Stage CKD and ESRD is an outcome measure to assess how well providers prevent mortality among patients with stage 4 or 5 CKD or ESRD. This measure assesses nephrology practices who care for adult Medicare Fee-for-Service (FFS) beneficiaries with late-stage CKD and ESRD.; **Measure Type:** Outcome; **Level of Analysis:** Clinician: Group/Practice; **Setting of Care:** Ambulatory Care; **Data Source:** Claims; Other (Beneficiary Enrollment data including the hospice enrollment, ESRD or dialysis enrollment).

Measure Steward/Developer Representatives at the Meeting

- Kyle Bagshaw

Standing Committee Votes

- **Evidence:** Total Votes-15; Pass-1; No Pass-14 (1/15 – 7%, No Pass).
- **Performance Gap:** Not taken
- **Reliability:** Not taken
- **Validity:** Not taken
- **Feasibility:** Not taken
- **Use:** Not taken
- **Usability:** Not taken
- **Standing Committee Recommendation for Endorsement:** Not taken

The standing committee did not recommend this measure for initial endorsement as it did not pass on evidence—a must-pass criterion.

This clinician group/practice-level measure was newly submitted for initial endorsement. This measure is not currently in use, but the developer shared plans for its use in the voluntary Kidney Care Choices model.

Prior to the meeting, this measure received five public comments. One comment was in support of the measure due to the need to drive improvement in CKD outcomes. The remaining four comments raised concern with staffing shortages in dialysis facilities, the attribution to nephrologists, how Stage 4 and 5 CKD were identified in the measure, lack of lab data for eGFR and albuminuria, and reliability at small case volumes. The committee considered these comments in its evaluation of the measure.

In its review of the evidence, some committee members raised concern with the level of attribution for this measure, given the team-based approach to renal care. A committee member noted that the evidence provided was very minimal and that one of the two studies cited was based on a study conducted from 2005 to 2006 in the United Kingdom. Further, the study was not designed to estimate the effect of the intervention on mortality. The second citation was a review article that primarily focused on cardiovascular-risk reduction and not all-cause mortality, with the exception of one of the cited studies in the review that did examine all-cause mortality but only in people with type 2 diabetes. Therefore, there was concern with respect to the measure including a broad population and all-cause mortality. Moving to a vote, the standing committee did not pass the measure on evidence. Therefore, the committee did not discuss or vote on any subsequent criteria.

The committee encouraged the developers to provide more evidence to support the specified level of attribution and suggested focusing on sub-populations and cause-specific mortality for any future resubmissions.

Public Comment

Dr. Pickering opened the lines for public comments. No public comments were provided during the measure evaluation meeting.

Next Steps

Dr. Pickering provided an overview of the next steps. The project team will begin drafting the meeting summary of the standing committee deliberations and will post this to the project webpage for a 20-day public comment period. The standing committee post-measure evaluation web meeting will take place on October 16 and the Consensus Standards Approval Committee review will take place on December 6. Lastly, Dr. Pickering and the chairs thanked the committee for their time, engagement, and participation in this work and adjourned the call.