

Spring 2023 Cycle

# PRIMARY CARE AND CHRONIC ILLNESS FINAL TECHNICAL REPORT

February 2024



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## Executive Summary

Primary care is a multidimensional framework that serves as the central medical resource for patients to access equitable and affordable quality health care. Primary care encompasses health maintenance and promotion, disease prevention, counseling, patient education, and diagnosis and treatment of acute and chronic illnesses. These facets of primary care and the management of chronic disease present the need for continuous quality care.

Quality measures are necessary tools for assessing improvements in primary care and the management of chronic illness, as well as the extent to which health care stakeholders are using evidence-based strategies to advance the quality of care. To support this effort, Battelle endorses and maintains performance measures through a standardized, consensus-based process.

For this project's measure review cycle, six measures were submitted for endorsement consideration (Table 1). Two measures (CBE #3753 and CBE #3754) were withdrawn from consideration by the developer due to the committee not passing the measure on evidence, a must-pass criterion. Of the remaining four measures, the committee recommended three measures for endorsement but did not recommend endorsement for one measure. The Consensus Standards Approval Committee (CSAC) upheld the committee's endorsement recommendations.

Effective March 27, 2023, the National Quality Forum (NQF) is no longer the consensus-based entity (CBE) funded through the Centers for Medicare & Medicaid Services (CMS) National Consensus Development and Strategic Planning for Health Care Quality Measurement Contract. Battelle has been selected to oversee the endorsement & maintenance (E&M) of clinical quality and cost/resource use measures. Since the Spring 2023 cycle launched at NQF, measures submitted to this E&M cycle continued along the prior E&M protocols that were in place at time of the Spring 2023 "Intent to Submit." Battelle took over the E&M work for the Spring 2023 when developers and/or stewards submitted their full measure information. To close out this E&M cycle, Battelle published the Spring 2023 measures for pre-evaluation public commenting, convened the E&M standing committees for their measure evaluation meetings, launched the Spring 2023 post-comment period, convened the E&M committees for the post-comment meeting, convened the CSAC to render a final endorsement decision, and executed the appeals period.

**Table 1. Measures Submitted for Endorsement Consideration**

Measure Number	Measure Title	New/Maintenance	Developer/Steward	Final Endorsement Decision
CBE #3210e	HIV Viral Suppression	Maintenance	Health Resources and Services Administration [HRSA] - HIV/AIDS Bureau	Endorsed

Measure Number	Measure Title	New/Maintenance	Developer/Steward	Final Endorsement Decision
CBE #3752e	HIV Annual Retention in Care	New	HRSA - HIV/AIDS Bureau	Endorsed
CBE #3755e	STI Testing for People with HIV	New	HRSA - HIV/AIDS Bureau	Endorsed
CBE #3742	ESRD Dialysis Patient Life Goals Survey (PaLS)	New	University of Michigan Kidney Epidemiology and Cost Center/ Centers for Medicare & Medicaid Services (CMS)	Not Endorsed
CBE #3753	Delay in Progression of Chronic Kidney Disease (CKD)	New	Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (Yale CORE)/CMS	Withdrawn - Not Endorsed
CBE #3754	Risk Standardized Mortality Ratio for Late-Stage Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD)	New	Yale CORE/CMS	Withdrawn - Not Endorsed

Summaries of the measure evaluation meetings are linked within the body of the report. Detailed summaries of the committee’s discussion and ratings of the criteria for each measure are in [Appendix A](#).

## Introduction

In the United States, chronic diseases are common and costly.<sup>1</sup> Broadly defined as conditions lasting one year or more and requiring ongoing medical attention or limiting daily activities or both, chronic diseases are the leading causes of death and disability in the U.S. In addition, these diseases, such as cancer, heart disease, and diabetes, are the leading drivers of the nation's \$4.1 trillion health care costs.<sup>2</sup> One important way individuals can reduce their chances of developing a chronic disease, or manage chronic diseases when they do occur, is by routinely accessing primary care. Regular checkups from a primary care physician (PCP) can improve health by preventing or detecting diseases early as well as providing educational opportunities for patients.<sup>3</sup>

Quality measures are tools to measure or quantify health care processes, outcomes, patient perceptions, and organizational structures and/or systems that are associated with the ability to provide high-quality health. Furthermore, quality metrics can be a powerful tool in helping identify substantial performance gaps in primary care and the management of chronic illness, affecting patient outcomes and overall costs.

Battelle, a CBE, convenes volunteer committees to evaluate and build consensus around quality measures for endorsement based on a standardized set of criteria. For the Spring 2023 cycle, the Primary Care and Chronic Illness (PCCI) standing committee reviewed measures focused on chronic kidney disease (CKD) and end-stage renal disease (ESRD), as well as care processes for individuals with the human immunodeficiency virus (HIV).

### Chronic Kidney Disease and End-Stage Renal Disease

CKD is the gradual loss of kidney function. ESRD occurs when CKD reaches an advanced stage and the kidneys no longer work to meet the body's needs, meaning that dialysis or a kidney transplant is needed to stay alive.<sup>4</sup> CKD affects more than one in seven U.S. adults—or an estimated 37 million Americans. Because early-stage kidney disease usually has no symptoms, as many as nine in 10 adults may have CKD without being aware of it. Medicare spending for beneficiaries with CKD (not including ESRD) ages 66 or older exceeded \$75 billion in 2020, representing 25.2% of Medicare spending in this age group. Nearly 808,000 people in the U.S. are living with ESRD, and Medicare spending related to ESRD totaled \$50.8 billion in 2020.<sup>5</sup>

### Human Immunodeficiency Virus

HIV attacks the immune system by destroying CD4 cells, which are vital to fighting off infection. Without these cells, people with untreated HIV are vulnerable to life-threatening infections and complications. Antiretroviral therapy is an effective HIV treatment; however, HIV remains a major global public health concern.<sup>6</sup> Approximately 1.2 million people in the U.S. have HIV, and about 13% of them are unaware of it. HIV also continues to disproportionately affect certain populations, such as racial and ethnic minorities, gay and bisexual people, and men who have

sex with men. HIV diagnoses are also not distributed evenly by region. In 2021, the South accounted for more than half of estimated new HIV infections.<sup>7</sup>

## Primary Care and Chronic Illness Measure Evaluation

For this measure review cycle, the Primary Care and Chronic Illness standing committee ([Appendix B](#)) evaluated five new measures and one measure undergoing maintenance review against standard measure evaluation criteria. Two measures (CBE #3753 and CBE #3754) were withdrawn from consideration by the developer due to the committee not passing the measure on evidence, a must-pass criterion (Table 2b).

**Table 2a. Number of Spring 2023 Primary Care and Chronic Illness Measures Submitted and Reviewed**

	Maintenance	New	Total
Number of measures submitted for endorsement review	1	5	6
Number of measures reviewed by the committee	1	5	6
Number of measures withdrawn from consideration*	0	2	2
Number of measures endorsed	1	1	2
Number of measures not endorsed	0	3	3

\*Measure developers/stewards can withdraw a measure from measure endorsement review at any point before the CSAC meeting. Table 2b provides a summary of withdrawn measures.

**Table 2b. Measures Withdrawn from Consideration**

Measure Number	Measure Title	Developer/Steward	New/Maintenance	Reason for Withdrawal*
CBE #3753	Delay in Progression of Chronic Kidney Disease (CKD)	Yale CORE/CMS	New	Withdrawn due to the committee not passing the measure on evidence, a must-pass criterion.
CBE #3754	Risk Standardized Mortality Ratio for Late-Stage Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD)	Yale CORE/CMS	New	Withdrawn due to the committee not passing the measure on evidence, a must-pass criterion.

\*Since both measures were withdrawn, they were not endorsed.



## Scientific Methods Panel Measure Evaluation

For the Spring 2023 cycle, the Scientific Methods Panel did not review any of the Primary Care and Chronic Illness measures due to the transition of the CBE.

## Comments Received Prior to Standing Committee Evaluation

Battelle accepts comments on measures under endorsement review through the [Partnership for Quality Measurement \(PQM\)<sup>TM</sup> website](#). For this evaluation cycle, the pre-evaluation commenting period opened on May 18, 2023, and closed on June 25, 2023. Thirty-four pre-evaluation comments were submitted and shared with the standing committee prior to the measure evaluation meeting on [July 31, 2023](#). Battelle received 18 comments for CBE #3742, one of which was in support of the measure, expressing its importance in advancing patient-centered care in ESRD quality and promoting the use of shared decision-making. The remaining 17 comments were non-supportive, raising concerns about the measure due to lack of appropriate testing, survey fatigue for patients with ESRD, and administrative burden to administer the survey. Additionally, comments from ESRD patients expressed concern with the appropriateness of surveying life goals without resulting action to achieve those life goals and emphasizing that survival is the primary life goal. The committee considered these comments in its evaluation of the measure.

Battelle received four for CBE #3210e, CBE #3752e, and CBE #3755e, one of which was in support of CBE #3755e due to its relevance, as sexually transmitted infections (STIs) are rising. The remaining three comments were non-supportive, raising concerns with the similarity of these three measures to other measures developed by the HIV/AIDS Bureau of HRSA.

For CBE #3753, Battelle received seven non-supportive comments, expressing 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 changes in the trajectory of the patient's illness. Lastly, for CBE #3754, Battelle received five comments, one of which was in support of the measure due to the need to drive improvement in CKD outcomes. The remaining four comments raised concerns with staffing shortages in dialysis facilities, the attribution of the measure to nephrologists, how Stages 4 and 5 CKD were identified in the measure, lack of lab data for glomerular filtration rates and albuminuria, and reliability at small case volumes.

The committee considered these comments in its evaluation of the measures. A summary of comments for each measure reviewed is provided in [Appendix A](#).

## Comments Received Post Standing Committee Evaluation

Following the standing committee's measure evaluation meeting, Battelle posted the committee endorsement recommendations on the [PQM website](#) for public comment. The commenting period opened on August 25, 2023, and closed on September 13, 2023. The committee received five comments, all pertaining to CBE #3755e and the committee's review of this

measure. One was from the developer in defense of the measure, expressing concern that there was insufficient subject matter expertise on the committee, which impacted the votes on importance and usability. The developer also stated that it believes the measure evaluation criteria were not applied appropriately for the validity criterion.

The other four comments were in support of CBE #3755e. Four comments addressed the committee's concern around the potential for introducing unintentional stigma for persons with HIV by mandating STI testing. The commenters responded by citing that increased standardized testing—in line with the Centers for Disease Control and Prevention's (CDC's) screening guidelines, which recommend, at minimum, annual testing for syphilis, gonorrhea, and chlamydia—is beneficial for reducing stigma and closing care gaps. Two comments specifically addressed the committee's concern that there was not sufficient correlation between annual testing and improved patient outcomes. One comment again cited the CDC screening guidelines, as well as guidance from the HIV Medicine Association, which both recommend, at minimum, annual STI testing to reduce infection rates, as evidence of the measure's importance. Lastly, one comment cited the substantial health losses caused by STIs and referenced studies that show that STI testing not only improves health outcomes for the patients, but for their partners as well.

Battelle convened the committee for the Spring 2023 post-comment web meeting on [October 16, 2023](#), to review the [full text of comments received](#) and to discuss and revote on evidence and validity for one measure (CBE #3755e) that did not achieve consensus on these must-pass criteria during the measure evaluation meeting, referred to as a “consensus not reached” (CNR) measure. A summary of comments for each measure reviewed is provided in [Appendix A](#).

## Summary of Potential High-Priority Gaps

During the standing committee's evaluation of the measures, no potential high-priority measurement gap areas were identified.

## Summary of Major Concerns or Methodological Issues

During the standing committee's evaluation of the measures, no major concerns or methodological issues emerged. Details of the standing committee's discussion and ratings of the criteria for each measure are included in [Appendix A](#).

## References

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## Appendix A: Details of Measure Evaluation

**Rating Scale:** H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

Battelle ensures that quorum is maintained for all live voting. A quorum is 66% of active standing committee members minus any recused standing committee members. Due to the exclusion of recused standing committee members from the quorum calculation, the required quorum for live voting may vary among measures. Quorum (12 out of 18 standing committee members for all measures) was reached and maintained throughout the full measure evaluation meeting on July 31, 2023. Vote totals may differ between measure criteria and between measures because standing committee members may have joined the meeting late, stepped away for a portion of the meeting, or had to leave the meeting before voting was complete. The vote totals listed below reflect the committee members present and eligible to vote at the time of the vote.

A measure is recommended for endorsement by the standing committee when greater than 60% of 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.

## A.1 Measures Endorsed

### *CBE #3210e - HIV Viral Suppression*

[Staff Assessment](#) | [Specifications](#)

**Numerator Statement:** Patients with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year. The outcome being measured is HIV viral suppression.

**Denominator Statement:** Patients, regardless of age, diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year who had at least one medical visit in the measurement year. The target population for this measure is all people living with HIV.

**Exclusions:** There are no patient exclusions.

**Adjustment/Stratification:** No risk adjustment or stratification

**Level of Analysis:** Facility

**Setting of Care:** Outpatient Services

**Type of Measure:** Outcome

**Data Source:** Electronic Health Records, Other Data Source

**Measure Steward:** Health Resources and Services Administration

**STANDING COMMITTEE EVALUATION**

**Table A.1-1.1 Importance to Measure and Report (MUST PASS)**

Criterion	Total Votes	Rationale
<b>1a. Evidence</b>	<ul style="list-style-type: none"> <li>Total Votes-15; Pass-15; No Pass-0 (15/15- 100%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The standing committee reviewed a logic model showing the continuum of care for HIV. This is an update to a prior logic model. The new model depicts structural inputs (HIV specialty clinicians, diagnostic laboratories, antiretroviral therapy (ART) linked with expected activities/processes (e.g., conduct HIV viral load tests; initiate and manage ART). The anticipated output of the activities is adherence to ART, which is linked with the short-term outcome of HIV viral suppression (the measure focus), which leads to long-term outcomes of improved health and reduced rates of HIV transmission.</li> <li>The standing committee also reviewed new evidence provided by the developer, including that HIV viral suppression continues to be a priority among the HIV community, that ART reduces the transmission of HIV, and that individual health care providers can have a significant amount of variation in viral suppression rates.</li> <li>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. None of the committee members reported knowing of new studies that contradicted the evidence base.</li> <li>The standing committee agreed that the measure was important and passed the measure on the evidence criterion.</li> </ul>
<b>1b. Performance Gap</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-1; M-14; L-0; I-0 (15/15- 100%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The committee agreed that the performance has improved since 2017. However, the committee noted that disparities remain, and an overall gap persists among racial/ethnic minority populations.</li> <li>The committee passed the measure on performance gap.</li> </ul>

**Table A.1-1.2. Scientific Acceptability of Measure Properties (MUST PASS)**

Criterion	Total Votes	Rationale
<b>2a. Reliability</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-1; M-14; L-0; I-0 (15/15- 100%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The standing committee reviewed the updated measure specifications and reliability testing, which was conducted at the accountable entity level using electronic health record data (EHR).</li> <li>The committee did not raise any concerns and passed the measure on reliability.</li> </ul>
<b>2b. Validity</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-0; M-15; L-0; I-0 (15/15- 100%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The standing committee reviewed submitted testing data (including new testing at the patient/encounter level and the accountable entity level) and discussed the threats to validity.</li> <li>Committee members did not express significant concerns related to validity during the discussion and voted to pass the measure on validity.</li> </ul>

**Table A.1-1.3. Feasibility**

Criterion	Total Votes	Rationale
<b>3. Feasibility</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-1; M-13; L-1; I-0 (14/15- 93.3%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The committee noted that EHR constraints may have implications on the ability to capture the diagnosis date consistently across study sites.                             <ul style="list-style-type: none"> <li>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.</li> </ul> </li> <li>The committee did not have any additional concerns and passed the measure on feasibility.</li> </ul>

**Table A.1-1.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)**

Criterion	Total Votes	Rationale
<b>4a. Use</b>	<ul style="list-style-type: none"> <li>Total Votes-15; Pass-14; No Pass-1 (14/15- 93.3%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>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.                             <ul style="list-style-type: none"> <li>During the meeting, the developer disclosed that this measure was selected for inclusion in the Merit-based Incentive Payment System (MIPS) for 2024 and is being considered for an infectious disease value pathway.</li> </ul> </li> <li>The committee had no further concerns and passed the measure on use.</li> </ul>
<b>4b. Usability</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-0; M-4; L-1; I-10 (4/15- 26.7%, No Pass)</li> </ul>	<ul style="list-style-type: none"> <li>Because 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.</li> <li>The committee did not pass the measure on usability.</li> </ul>

**Table A.1-1.5. Related and Competing Measures**

Criterion	Related and/or Competing Measure(s)	Rationale
<b>5. Related and Competing</b>	<ul style="list-style-type: none"> <li>CBE #3209e</li> <li>CBE #3211e</li> <li>CBE #0409</li> <li>CBE #2080</li> <li>CBE #0405</li> </ul>	<ul style="list-style-type: none"> <li>This measure was identified as related to the following measures: CBE #3209e [HIV Medical Visit Frequency], CBE #3211E [Prescription of HIV Antiretroviral Therapy], CBE #0409 [HIV/AIDS: Sexually Transmitted Diseases – Screening for Chlamydia, Gonorrhea, and Syphilis], CBE #2080 [Gap in HIV medical visits], and CBE #0405 [HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis].</li> <li>The developer shared that CBE #0409 and CBE #0405 will be retired.</li> <li>The committee did not have any concerns with the other related measures, noting there was not much overlap.</li> </ul>

**Table A.1-1.6. Standing Committee Recommendation for Endorsement**

Committee Endorsement Recommendation	Total Votes	Rationale
<b>Recommended for Endorsement</b>	<ul style="list-style-type: none"> <li>Total Votes-15; Yes-15; No-0 (15/15- 100%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The committee voted to recommend the measure for continued endorsement.</li> </ul>

**Table A.1-1.7. Public and Member Comment**

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
<b>Non-supportive comments</b>	<ul style="list-style-type: none"> <li>One</li> </ul>	<p><i>Pre-evaluation</i></p> <ul style="list-style-type: none"> <li>Concern with the similarity of these three measures to other measures developed by the HIV/AIDS Bureau of HRSA.</li> </ul> <p><i>Post-evaluation</i></p> <ul style="list-style-type: none"> <li>None</li> </ul>



**CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION**

**Table A.1-1.8. CSAC Endorsement Decision**

CSAC Endorsement Decision	Total Votes	Rationale
<b>Endorsed</b>	<ul style="list-style-type: none"> <li>Total Votes-10; Yes-10; No-0 (10/10- 100%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>Approved via consent calendar.</li> </ul>

**APPEALS BOARD EVALUATION**

**Table A.1-1.9. Appeals**

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
<b>No</b>	<ul style="list-style-type: none"> <li>No</li> </ul>	N/A

*CBE #3752e - HIV Annual Retention in Care*

[Staff Assessment](#) | [Specifications](#)

**Numerator Statement:** Number of patients who had at least two eligible encounters or at least one eligible encounter and one HIV viral load test at least 90 days apart within a 12-month measurement year.

**Denominator Statement:** All patients, regardless of age, with a diagnosis of HIV during the first 8 months of the measurement period or before the measurement period who had at least one eligible encounter during the first 8 months of the measurement period.

**Exclusions:** Not applicable.

**Adjustment/Stratification:** No risk adjustment or risk stratification.

**Level of Analysis:** Clinician: Individual

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Electronic Health Records

**Measure Steward:** Health Resources and Services Administration – HIV/AIDS Bureau

**STANDING COMMITTEE EVALUATION**

**Table A.1-2.1 Importance to Measure and Report (MUST PASS)**

Criterion	Total Votes	Rationale
<b>1a. Evidence</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-1; M-13; L-1; I-0 (14/15, 93.3%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>Standing committee members reviewed a logic model that depicts structural inputs (HIV specialty clinicians, diagnostic laboratories) linked with expected activities/processes (provide ongoing clinical visits, conduct HIV viral load tests). The anticipated output of the activities is adherence to antiretroviral therapy (ART), which is linked with the short-term outcome of HIV viral suppression, leading to long-term outcomes of improved health and reduced rates of HIV transmission. They also reviewed evidence provided by the developer, which included two sets of clinical practice guidelines from the Panel on Antiretroviral Guidelines for Adults and Adolescents and the International Association of Physicians in AIDS care panel.</li> <li>Committee members noted that most of the evidence was from 2011 or earlier but felt that a more recent guideline from 2019 strengthened prior evidence.</li> <li>The committee did not raise additional concerns and voted to pass the measure on evidence.</li> </ul>

Criterion	Total Votes	Rationale
<b>1b. Performance Gap</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-1; M-9; L-4; I-1 (10/15- 66.7%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The standing committee discussed whether the data are generalizable, as they came from patients from the Ryan White HIV/AIDS program clinical studies. The committee noted that these sites are often held to higher performance standards and oversight due to federal funding, which could potentially skew the performance rates.                             <ul style="list-style-type: none"> <li>The developer responded 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.</li> </ul> </li> <li>The committee voted to pass the measure on performance gap.</li> </ul>

**Table A.1-2.2. Scientific Acceptability of Measure Properties (MUST PASS)**

Criterion	Total Votes	Rationale
<b>2a. Reliability</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-8; M-5; L-2; I-0 (13/15- 86.7%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The standing committee reviewed reliability testing conducted at the accountable entity level.</li> <li>The committee raised no concerns about reliability.</li> </ul>
<b>2b. Validity</b>	<ul style="list-style-type: none"> <li>Total Votes-14; H-0; M-12; L-1; I-1 (12/14- 85.7%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The standing committee reviewed validity testing conducted at the patient/encounter level and the accountable entity level.</li> <li>The committee drew attention to accuracy issues of two data elements (“Encounter Performed: Home Healthcare Services” and “Encounter Performed: Outpatient Consultation”) as they were not available at one or more of the test sites.                             <ul style="list-style-type: none"> <li>The developer indicated that neither is required to calculate the measure.</li> </ul> </li> <li>The committee voted to pass the measure without major concerns regarding validity.</li> </ul>

**Table A.1-2.3. Feasibility**

Criterion	Total Votes	Rationale
<b>3. Feasibility</b>	<ul style="list-style-type: none"> <li>Total Votes-14; H-1; M-13; L-0; I-0 (14/14- 100%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The committee discussed EHRs’ ability to routinely capture the data required for this measure. They decided that, for sites lacking structured data fields, unstructured methods could be used to calculate the measure as specified.</li> <li>The committee passed the measure on feasibility.</li> </ul>

**Table A.1-2.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)**

Criterion	Total Votes	Rationale
<b>4a. Use</b>	<ul style="list-style-type: none"> <li>Total Votes-14; Pass-14; No Pass-0 (14/14-100%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The committee acknowledged the planned use of the measure as part of MIPS in 2024 and passed the measure on the use criterion.</li> </ul>
<b>4b. Usability</b>	<ul style="list-style-type: none"> <li>Total Votes-14; H-1; M-9; L-4; I-0 (10/14- 71.4%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>Some committee members questioned how results of this metric might be used to effectively increase adherence to best practice.</li> <li>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.</li> <li>The committee passed the measure on usability.</li> </ul>

**Table A.1-2.5. Related and Competing Measures**

Criterion	Related and/or Competing Measure(s)	Rationale
<b>5. Related and Competing</b>	<ul style="list-style-type: none"> <li>CBE #3209e</li> <li>CBE #3210e</li> <li>CBE #3211e</li> <li>CBE #0405</li> </ul>	<ul style="list-style-type: none"> <li>This measure was identified as related to the following measures: CBE #3209e [HIV Medical Visit Frequency], CBE #3210e [HIV Viral Suppression], CBE #3211e [Prescription of HIV Antiretroviral Therapy], CBE #0405 [HIV/AIDS: Pneumocystis Jirovecii Pneumonia (PCP) Prophylaxis].</li> <li>The developer stated that CBE #0405 will be retired.</li> <li>With CBE #3752e’s adoption into MIPS, the developer will be recommending the removal of CBE #3209e.</li> <li>The committee did not have any comments or concerns.</li> </ul>

**Table A.1-2.6. Standing Committee Recommendation for Endorsement**

Committee Endorsement Recommendation	Total Votes	Rationale
<b>Recommended for Endorsement</b>	<ul style="list-style-type: none"> <li>Total Votes-14; Yes-13; No-1 (13/14- 92.9%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The standing committee voted to recommend the measure for endorsement.</li> </ul>

**Table A.1-2.7. Public and Member Comment**

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
<b>Non-supportive comments</b>	<ul style="list-style-type: none"> <li>One</li> </ul>	<p><i>Pre-evaluation</i></p> <ul style="list-style-type: none"> <li>Concern with the similarity of these three measures to other measures developed by the HIV/AIDS Bureau of HRSA.</li> </ul> <p><i>Post-evaluation</i></p> <ul style="list-style-type: none"> <li>None</li> </ul>

**CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION**

**Table A.1-1.8. CSAC Endorsement Decision**

CSAC Endorsement Decision	Total Votes	Rationale
<b>Endorsed</b>	<ul style="list-style-type: none"> <li>Total Votes-10; Yes-10; No-0 (10/10- 100%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>Approved via consent calendar.</li> </ul>

## APPEALS BOARD EVALUATION

**Table A.1-1.9. Appeals**

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
No	• No	N/A

*CBE #3755e - STI Testing for People with HIV*

[Staff Assessment](#) | [Specifications](#)

**Numerator Statement:** Patients who had a test for syphilis, a test for gonorrhea, and a test for chlamydia performed at least once during the measurement period.

**Denominator Statement:** All patients 13 years of age and older with a diagnosis of HIV before the end of the measurement period seen for an eligible encounter during the measurement period.

**Exclusions:** Not applicable.

**Adjustment/Stratification:** No risk adjustment or stratification.

**Level of Analysis:** Clinician: Individual

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Electronic Health Records

**Measure Steward:** Health Resources and Services Administration – HIV/AIDS Bureau

**STANDING COMMITTEE EVALUATION**

**Table A.1-3.1. Importance to Measure and Report (MUST PASS)**

Criterion	Total Votes	Rationale
<b>1a. Evidence</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-0; M-7; L-7; I-1 (7/15- 46.7%, No Pass)</li> <li>Post-comment Evidence Revote: Total Votes: 12; H-0; M-9; L-3; I-0 (9/12- 75%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The standing committee reviewed a logic model that depicts structural inputs (e.g., HIV specialty clinicians, diagnostic laboratories) linked with expected activities/processes (e.g., conduct syphilis, gonorrhea, and chlamydia tests). The output of the activities is identification of patients with these STIs, which is linked with the anticipated outcome of treatment for the STIs. They also reviewed evidence provided by the developer, including three sets of clinical guidelines from the Panel on Opportunistic Infections in Adults and Adolescents with HIV, Sexually Transmitted Infections Treatment Guidelines and the United States Preventative Services Task Force (USPSTF).</li> <li>The standing committee questioned why syphilis, gonorrhea, and chlamydia were all included on the same measure.                         <ul style="list-style-type: none"> <li>The developer responded by saying this was at the request of CMS.</li> <li>The committee noted the evidence for including syphilis was the strongest. They said the evidence for including gonorrhea and chlamydia was suitable.</li> <li>Some members were concerned that there was no option for providers if they tested for only one or two of the STIs.</li> </ul> </li> <li>The committee also expressed concern over the frequency of testing, as the evidence suggests testing should be conducted annually or more frequently for certain individuals.</li> <li>During the August 2023 Measure Evaluation Meeting, the committee did not reach consensus on evidence.</li> </ul>

Criterion	Total Votes	Rationale
		<ul style="list-style-type: none"> <li>During the November 2023 Post-Comment Meeting, the developer stated that the increase in STI testing would lead to improved outcomes both for the individual and the population, underscoring the increasing percentage of STI cases in persons with HIV.                             <ul style="list-style-type: none"> <li>The developer reaffirmed that information about an individual’s sexual activity is not available as structured fields in the electronic health record. However, the measure results range from 35 – 55% across sites, and assuming those patients who are not sexually active or in a monogamous relationship are evenly distributed across those sites, they would not increase the measure results by much if they are not being captured in the measure already.</li> <li>The developer further stated it did not expect to achieve 100% on this measure, but there is clear evidence to show screening for STIs in people with HIV is low, even if patients who opt out make up 10% or even 20% of these patients.</li> </ul> </li> <li>The standing committee then recognized the importance of this measure and passed the measure on evidence.</li> </ul>
<b>1b. Performance Gap</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-0; M-12; L-3; I-0 (12/15- 80%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>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.</li> <li>The committee voted to pass the measure on performance gap.</li> </ul>

**Table A.1-3.2. Scientific Acceptability of Measure Properties (MUST PASS)**

Criterion	Total Votes	Rationale
<b>2a. Reliability</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-9; M-4; L-1; I-1 (14/15- 93.3%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The standing committee reviewed reliability testing conducted at the patient/encounter-level.</li> <li>The committee did not have any major concerns and passed the measure on reliability.</li> </ul>



Criterion	Total Votes	Rationale
<b>2b. Validity</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-0; M-7; L-8; I-0 (7/15- 46.7%, No Pass)</li> <li>Post-comment Validity Revote: Total Votes: 12; H-1; M-9; L-2; I-0 (10/12- 83.3%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>During the committee’s measure evaluation meeting, consensus was not reached validity.</li> <li>Despite sufficient data element validity and construct validity, several committee members raised concern with the face validity testing, as three of the seven (43%) clinicians on the developer-convened panel agreed the measure can distinguish quality of care. This result was due to a concern that patients who are not sexually active would opt out of screening.                             <ul style="list-style-type: none"> <li>During the post-evaluation comment period, the committee received five supportive comments from individuals and organizations, all pertaining to CBE #3755e and the committee’s review of this measure.</li> </ul> </li> <li>During the post-evaluation comment meeting, the developer posited that STI testing would lead to improved outcomes both for the individual and the population.                             <ul style="list-style-type: none"> <li>The developer reaffirmed that information about an individual’s sexual activity is not available as structured fields in the electronic health record.</li> <li>In addition, the developer stated the measure results range from 35% to 55% across sites, and assuming those patients who are not sexually active or in a monogamous relationship are evenly distributed across those sites, they would not increase the measure results by much if they are not being captured in the measure already.</li> <li>The developer further stated it did not expect to achieve 100% on this measure, but there is clear evidence to show screening for STIs in people with HIV is low, even if patients who opt out make up 10% or even 20% of these patients.</li> </ul> </li> <li>After considering this information, the committee voted to pass the measure on validity during the November 2023 Post-Comment Meeting.</li> </ul>

**Table A.1-3.3. Feasibility**

Criterion	Total Votes	Rationale
<b>3. Feasibility</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-0; M-15; L-0; I-0 (15/15- 100%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>Raising no concerns, committee members voted to pass feasibility criteria based on the prior discussion for CBE #3752e.</li> </ul>

**Table A.1-3.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)**

Criterion	Total Votes	Rationale
<b>4a. Use</b>	<ul style="list-style-type: none"> <li>Total Votes-15; Pass-12; No Pass-3 (12/15-80%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>Committee members recognized the measure’s planned use in MIPS in 2024 and passed the measure on use.</li> </ul>
<b>4b. Usability</b>	<ul style="list-style-type: none"> <li>Total Votes-15; H-0; M-9; L-6; I-0 (9/15- 60%, No Pass)</li> </ul>	<ul style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>Ultimately, the committee did not pass the measure on usability.</li> </ul>

**Table A.1-3.5. Related and Competing Measures**

Criterion	Related and/or Competing Measure(s)	Rationale
<b>5. Related and Competing</b>	<ul style="list-style-type: none"> <li>CBE #3209e</li> <li>CBE #3210e</li> <li>CBE #3211e</li> <li>CBE #0409</li> </ul>	<ul style="list-style-type: none"> <li>This measure was identified as related to the following measures: CBE #3209e [HIV Medical Visit Frequency], CBE #3210e [HIV Viral Load Suppression], CBE #3211e [Prescription of HIV Antiretroviral Therapy], CBE #0409 [HIV/AIDS: Sexually Transmitted Diseases – Screening for Chlamydia, Gonorrhea, and Syphilis].</li> <li>However, since the committee did not have quorum during the post-comment meeting, a related and competing measure discussion was not conducted.</li> </ul>

**Table A.1-3.6. Standing Committee Recommendation for Endorsement**

Committee Endorsement Recommendation	Total Votes	Rationale
<b>Recommended for Endorsement</b>	<ul style="list-style-type: none"> <li>Total Votes: 12; Yes-9; No-3 (9/12- 75%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>After the committee passed the measure on evidence and validity during the Post-Comment Meeting revote, it recommended the measure for endorsement.</li> </ul>

**Table A.1-3.7. Public and Member Comment**

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
<b>Supportive comments</b>	<ul style="list-style-type: none"> <li>Six</li> </ul>	<p><i>Pre-evaluation</i></p> <ul style="list-style-type: none"> <li>One comment expressed support for the measure’s relevance, as sexually transmitted infections (STIs) are rising.</li> </ul> <p><i>Post-evaluation</i></p> <ul style="list-style-type: none"> <li>Four comments expressed support of the measure by addressing the committee’s concern around the potential for introducing unintentional stigma for persons with HIV by mandating STI testing.                             <ul style="list-style-type: none"> <li>The commenters responded by citing that increased standardized testing in line with the CDC’s screening guidelines, which recommend at minimum annual testing for syphilis, gonorrhea, and chlamydia is beneficial for reducing stigma and closing care gaps.</li> <li>Two comments specifically addressed the committee’s concern that there was not sufficient correlation between annual testing and improved patient outcomes.</li> <li>One comment again cited the CDC screening guidelines, as well as guidance from the HIV Medicine Association, which both recommend, at a minimum, annual STI testing to reduce infection rates, as evidence of the measure’s importance.</li> <li>Lastly, one comment cited the substantial health losses caused by STIs and referenced studies that show that STI testing not only improves health outcomes for the patients, but for their partners as well.</li> </ul> </li> <li>One comment was from the developer in defense of the measure, expressing concern that there was insufficient subject matter expertise on the committee, which impacted the votes on importance and usability. The developer also stated that it believes the measure evaluation criteria were not applied appropriately for the validity criterion.</li> </ul>
<b>Non-supportive comments</b>	<ul style="list-style-type: none"> <li>One</li> </ul>	<p><i>Pre-evaluation</i></p> <ul style="list-style-type: none"> <li>Concern with the similarity of these three measures to other measures developed by the HIV/AIDS Bureau of HRSA.</li> </ul>

**CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION**

**Table A.1-3.8. CSAC Endorsement Decision**

CSAC Endorsement Decision	Total Votes	Rationale
<b>Endorsed</b>	<ul style="list-style-type: none"> <li>Total Votes-10; Yes-10; No-0 (10/10- 100%, Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The CSAC voted to uphold the standing committee’s recommendation.</li> <li>It noted that after the public comment period, the standing committee’s concerns were addressed.</li> <li>Several CSAC members also found the standing committee’s process for reviewing and re-reviewing the measure to be appropriate.</li> <li>One committee member spoke in favor of CBE #3755e due to the rising rates of STIs.</li> </ul>

**APPEALS BOARD EVALUATION**

**Table A.1-1.9. Appeals**

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
<b>No</b>	<ul style="list-style-type: none"> <li>No</li> </ul>	N/A

## A.2 Measures Not Endorsed

### *CBE #3742 - ESRD Dialysis Patient Life Goals (PaLS)*

[Staff Assessment](#) | [Specifications](#)

**Numerator Statement:** The numerator is the number of eligible patients from the denominator that completed at least one scorable item of the PaLS (i.e., at least one of the six Likert-type items).

**Denominator Statement:** All prevalent adult chronic dialysis patients ( $\geq 18$  y/o) treated by the facility (both In-Center and Home Dialysis) for greater than 90 days during the reporting period, who read and understand English.

**Exclusions:** Exclusions are implicit based on eligibility criteria to complete the survey. These include age less than 18; patient has a kidney transplant; patient with recovered renal function or lost to follow up; and unable to read and/or understand English (whether self-assessed or self-reported). In our testing we also excluded duplicate patient surveys.

**Adjustment/Stratification:** No risk adjustment or stratification

**Level of Analysis:** Other: US Chronic Dialysis Population (Patient-Level). The measure testing was performed on a sample that reflected the US chronic dialysis population at the patient level.

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Claims data, Instrument based data, Registry Data

**Measure Steward:** Centers for Medicare and Medicaid Services

**STANDING COMMITTEE EVALUATION**

**Table A.2-1.1. Importance to Measure and Report (MUST PASS)**

Criterion	Total Votes	Rationale
<b>1a. Evidence</b>	<ul style="list-style-type: none"> <li>Total Votes-16; H-0; M-2; L-13; I-1 (2/16- 12.5%, No Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The standing committee reviewed a logic model of, which depicted the identification of patient life goals (Patient life goal survey) would lead to a discussion of different treatment plans (e.g., dialysis or transplant modality; vascular access type) and shared decision-making. This would promote alignment of treatment plan with life goals and patient-centered care. The developer also provided evidence from CMS regulation, the updated National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative Guideline Statements, and studies suggesting that about 30 percent of ESRD patients do not feel they are adequately informed or included in the decision-making about treatment modality options.</li> <li>Committee members shared concerns that the provided evidence did not show a clear patient desire for this type of measurement and that the measure lacked alignment with patient-preferred outcomes. The committee suggested that the developer consider ways to clearly show that ESRD patients value this type of outcome.</li> <li>The committee also stated there needs to be more evidence to clearly indicate how this measure will improve patient outcomes.</li> <li>Ultimately, the standing committee did not pass the measure on evidence.</li> </ul>
<b>1b. Performance Gap</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on performance gap as the measure did not pass on evidence, a must-pass criterion.</li> </ul>

**Table A.2-1.2. Scientific Acceptability of Measure Properties (MUST PASS)**

Criterion	Total Votes	Rationale
<b>2a. Reliability</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on reliability as the measure did not pass on evidence, a must-pass criterion.</li> </ul>
<b>2b. Validity</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on validity as the measure did not pass on evidence, a must-pass criterion.</li> </ul>

**Table A.2-1.3. Feasibility**

Criterion	Total Votes	Rationale
<b>3. Feasibility</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on feasibility as the measure did not pass on evidence, a must-pass criterion.</li> </ul>

**Table A.2-1.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)**

Criterion	Total Votes	Rationale
<b>4a. Use</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on use as the measure did not pass on evidence, a must-pass criterion.</li> </ul>
<b>4b. Usability</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on usability as the measure did not pass on evidence, a must-pass criterion.</li> </ul>

**Table A.2-1.5. Related and Competing Measures**

Criterion	Related and/or Competing Measure(s)	Rationale
<b>5. Related and Competing</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss related and competing measures, as the measure did not pass on evidence, a must-pass criterion.</li> </ul>

**Table A.2-1.6. Standing Committee Recommendation for Endorsement**

Committee Endorsement Recommendation	Total Votes	Rationale
<b>Not Recommended for Endorsement</b>	N/A	<ul style="list-style-type: none"> <li>The standing committee did not recommend this measure for initial endorsement as it did not pass on evidence, a must-pass criterion.</li> </ul>

**Table A.2-1.7. Public and Member Comment**

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
<b>Supportive comments</b>	<ul style="list-style-type: none"> <li>One</li> </ul>	<i>Pre-evaluation</i> <ul style="list-style-type: none"> <li>One comment expressed the measure’s importance in advancing patient-centered care in ESRD quality and promoting the use of shared decision-making.</li> </ul>

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
<b>Non-supportive comments</b>	<ul style="list-style-type: none"> <li>Seventeen</li> </ul>	<p><i>Pre-evaluation</i></p> <ul style="list-style-type: none"> <li>Concerns about 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 expressed concern with the appropriateness for surveying life goals without resulting action to achieve those life goals and that survival is the primary life goal.</li> </ul>

**CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION**

**Table A.2-1.8. CSAC Endorsement Decision**

CSAC Endorsement Decision	Total Votes	Rationale
<b>Not Endorsed</b>	<ul style="list-style-type: none"> <li>Total Votes-11; Yes-11; No-0 (11/11- 100%, Pass to Not Endorse)</li> </ul>	<ul style="list-style-type: none"> <li>CSAC voted to uphold the standing committee’s recommendation.</li> <li>The CSAC did not have any concerns, nor questions, and agreed that the feedback from the standing committee to the developer seemed reasonable.</li> </ul>

**APPEALS BOARD EVALUATION**

**9. Appeals:**

- Based on the prior consensus-based entity’s process, only endorsed measures are eligible for any appeal.



*CBE #3753 - Delay in Progression of Chronic Kidney Disease (CKD)*

[Staff Assessment](#) | [Specifications](#)

**Numerator Statement:** The measure outcome is progression from Stage 4 CKD to ESRD requiring chronic dialysis in the measurement year for patients aged 19 and older with stage 4 CKD. The outcome of interest is defined as enrollment in ESRD or ESRD-Dialysis Medicare coverage. Not all possible patient events will be counted in the numerator.

**Denominator Statement:** The cohort includes Medicare Fee-For-Service beneficiaries (patients) who are 19 years and older, with Stage 4 CKD, who are not enrolled in Medicare ESRD or ESRD-dialysis, who are not enrolled in Medicare hospice, who have not had a kidney transplant within the past 12 months, and who are being treated by a nephrology practice.

**Exclusions:** The cohort excludes patients with advanced or metastatic cancer, defined as specific cancer-related ICD-10 codes from an inpatient encounter.

**Adjustment/Stratification:** Statistical Risk Model

**Level of Analysis:** Clinician: Group/Practice

**Setting of Care:** Ambulatory Care

**Type of Measure:** Outcome

**Data Source:** Claims Data, Beneficiary Enrollment Data

**Measure Steward:** Centers for Medicare and Medicaid Services

**STANDING COMMITTEE EVALUATION**

**Table A.2-2.1. Importance to Measure and Report (MUST PASS)**

Criterion	Total Votes	Rationale
<b>1a. Evidence</b>	<ul style="list-style-type: none"> <li>Total Votes-16; Pass-0; No Pass-16 (0/16- 0%, No Pass)</li> </ul>	<ul style="list-style-type: none"> <li>Standing committee members reviewed a logic model that depicts how services from nephrology providers can achieve a delay in initiation of dialysis, which tends to provide improved patient-centered care and quality of life and reduction of comorbidities associated with dialysis. The developer cited multiple studies supporting the positive outcomes including longer survival, greater quality of life, and greater patient engagement in treatment choices associated with delayed dialysis, and multiple studies associating the initiation of dialysis with a high-risk burden to patients, including risk of infection, pain from dialysis procedures, and high psychosocial impact. The developer cited a randomized controlled trial which found that a 6-month delay in dialysis resulted in savings of \$18,000 (otherwise spent on the dialysis treatment plus transportation and hospitalizations) with no difference in quality of life or survival.</li> <li>Committee members commented on the age of some of the studies provided, noting that the developer had evidently overlooked more recent, relevant studies. The committee questioned the suitability of some of the older studies cited, with some committee members noting that the provided evidence refers to certain interventions that are not consistent with standard of care, such as erythropoiesis-stimulating agents.                         <ul style="list-style-type: none"> <li>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 the 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.</li> </ul> </li> <li>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.</li> <li>The standing committee did not pass the measure on evidence.</li> </ul>
<b>1b. Performance Gap</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on performance gap, as the measure did not pass on evidence.</li> </ul>

**Table A.2-2.2. Scientific Acceptability of Measure Properties (MUST PASS)**

Criterion	Total Votes	Rationale
<b>2a. Reliability</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on reliability, as the measure did not pass on evidence.</li> </ul>
<b>2b. Validity</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on validity, as the measure did not pass on evidence.</li> </ul>

**Table A.2-2.3. Feasibility**

Criterion	Total Votes	Rationale
<b>3. Feasibility</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on feasibility, as the measure did not pass on evidence.</li> </ul>

**Table A.2-2.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)**

Criterion	Total Votes	Rationale
<b>4a. Use</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on use, as the measure did not pass on evidence.</li> </ul>
<b>4b. Usability</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on usability, as the measure did not pass on evidence.</li> </ul>

**Table A.2-2.5. Related and Competing Measures**

Criterion	Related and/or Competing Measure(s)	Rationale
<b>5. Related and Competing</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss related and competing measures, as the measure did not pass on evidence, a must-pass criterion.</li> </ul>

**Table A.2-2.6. Standing Committee Recommendation for Endorsement**

Committee Endorsement Recommendation	Total Votes	Rationale
<b>Not Recommended for Endorsement</b>	N/A	<ul style="list-style-type: none"> <li>The standing committee did not recommend this measure for initial endorsement, as it did not pass on evidence.</li> </ul>

**Table A.2-2.7. Public and Member Comment**

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
<b>Non-supportive comments</b>	<ul style="list-style-type: none"> <li>Seven</li> </ul>	<p><i>Pre-evaluation</i></p> <ul style="list-style-type: none"> <li>Concerns regarding staffing shortages in dialysis facilities and testing and specification concerns, including risk adjustment and exclusions.</li> <li>One comment noted that this measure may limit a provider’s ability to make meaningful change in the trajectory of the patient’s illness.</li> </ul>

**CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION**

**Table A.2-2.8. CSAC Endorsement Decision**

CSAC Endorsement Decision	Total Votes	Rationale
<b>Not Endorsed</b>	N/A	<ul style="list-style-type: none"> <li>The CSAC did not evaluate this measure as the developer withdrew the measure due to the committee not passing the measure on evidence, a must-pass criterion.</li> </ul>

**APPEALS BOARD EVALUATION**

**9. Appeals:**

- Based on the prior consensus-based entity’s process, only endorsed measures are eligible for any appeal.

*CBE #3754 [Risk Standardized Mortality Rate for Late-Stage Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD)]*

[Staff Assessment](#) | [Specifications](#)

**Numerator Statement:** The measure outcome is all-cause mortality within the measurement year. Mortality is defined as death for any reason within the measurement period for patients aged 19 and older with Stage 4 CKD, Stage 5 CKD, or ESRD at risk during the measurement period. Hospice enrollment is a censoring event and mortality after enrollment is not counted to the outcome.

**Denominator Statement:** The cohort includes Medicare Fee-For-Service beneficiaries (patients) who are 19 years and older with Stage 4 CKD, Stage 5 CKD, or ESRD and who are being treated by a nephrology practice. Patients are not included if they are enrolled in Medicare hospice or have had a kidney transplant within the past 12 months.

**Exclusions:** The measure excludes patients with metastatic and advanced cancers, defined as specific cancer-related ICD-10 codes from an inpatient encounter.

**Adjustment/Stratification:** Statistical risk model

**Level of Analysis:** Clinician: Group/Practice

**Setting of Care:** Ambulatory Care

**Type of Measure:** Outcome

**Data Source:** Claims Data, Beneficiary Enrollment Data

**Measure Steward:** Centers for Medicare and Medicaid Services

**STANDING COMMITTEE EVALUATION**

**Table A.2-3.1. Importance to Measure and Report (MUST PASS)**

Criterion	Total Votes	Rationale
<b>1a. Evidence</b>	<ul style="list-style-type: none"> <li>Total Votes-15; Pass-1; No Pass-14 (1/15- 6.7%, No Pass)</li> </ul>	<ul style="list-style-type: none"> <li>The standing committee reviewed a logic model that depicts how services (including delivery of timely, high-quality, evidence-based care to patients with CKD and ESRD; improving care coordination among clinical providers and patients; and support for adequate disease self-management) from nephrology providers can lead to better care processes, which lead to lower rates of mortality for CKD and ESRD patients. The developer also cited multiple studies supporting interventions aimed at improving the quality of life for patients with CKD and ESRD.</li> <li>Some committee members raised concern with the level of attribution for this measure, given the team-based approach to renal care.</li> <li>A committee member noted that the provided evidence 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, except for 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.</li> <li>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.</li> <li>The committee did not pass the measure on evidence.</li> </ul>
<b>1b. Performance Gap</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on performance gap, as the measure did not pass on evidence.</li> </ul>

**Table A.2-3.2. Scientific Acceptability of Measure Properties (MUST PASS)**

Criterion	Total Votes	Rationale
<b>2a. Reliability</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on reliability, as the measure did not pass on evidence.</li> </ul>
<b>2b. Validity</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on validity, as the measure did not pass on evidence.</li> </ul>

**Table A.2-3.3. Feasibility**

Criterion	Total Votes	Rationale
<b>3. Feasibility</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on feasibility, as the measure did not pass on evidence.</li> </ul>

**Table A.2-3.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)**

Criterion	Total Votes	Rationale
<b>4a. Use</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on use, as the measure did not pass on evidence.</li> </ul>
<b>4b. Usability</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or vote on usability, as the measure did not pass on evidence.</li> </ul>

**Table A.2-3.5. Related and Competing Measures**

Criterion	Related and/or Competing Measure(s)	Rationale
<b>5. Related and Competing</b>	N/A	<ul style="list-style-type: none"> <li>The committee did not discuss or related and competing, as the measure did not pass on evidence, a must-pass criterion.</li> </ul>

**Table A.2-3.6. Standing Committee Recommendation for Endorsement**

Committee Endorsement Recommendation	Total Votes	Rationale
<b>Not Recommended for Endorsement</b>	N/A	<ul style="list-style-type: none"> <li>The standing committee did not recommend this measure for initial endorsement as it did not pass on evidence.</li> </ul>

**Table A.2-3.7. Public and Member Comment**

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
<b>Supportive comments</b>	<ul style="list-style-type: none"> <li>One</li> </ul>	<p><i>Pre-evaluation</i></p> <ul style="list-style-type: none"> <li>Support of the measure due to the need to drive improvement in CKD outcomes.</li> </ul> <p><i>Post-evaluation</i></p> <ul style="list-style-type: none"> <li>None</li> </ul>
<b>Non-supportive comments</b>	<ul style="list-style-type: none"> <li>Four</li> </ul>	<p><i>Pre-evaluation</i></p> <ul style="list-style-type: none"> <li>Concerns with staffing shortages in dialysis facilities, the attribution of the measure to nephrologists, how Stages 4 and 5 CKD were identified in the measure, lack of lab data for glomerular filtration rates and albuminuria, and reliability at small case volumes.</li> </ul> <p><i>Post-evaluation</i></p> <ul style="list-style-type: none"> <li>None</li> </ul>

**CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION**

**Table A.2-3.8. CSAC Endorsement Decision**

CSAC Endorsement Decision	Total Votes	Rationale
<b>Not Endorsed</b>	N/A	<ul style="list-style-type: none"> <li>The CSAC did not evaluate this measure, as the developer withdrew the measure due to the committee not passing the measure on evidence, a must-pass criterion.</li> </ul>

**APPEALS BOARD EVALUATION**

**9. Appeals:**

- Based on the prior consensus-based entity’s process, only endorsed measures are eligible for any appeal.



## Appendix B: Primary Care and Chronic Illness Standing Committee and Battelle Staff

### PRIMARY CARE AND CHRONIC ILLNESS STANDING COMMITTEE

**Dale Bratzler, DO, MPH (Co-Chair)**

Chief Quality Officer, OU Physicians  
Oklahoma University Health Sciences Center

**Adam Thompson, BA (Co-Chair)**

Consultant

**Kim Elliott, PhD**

Executive Director  
Health Services Advisory Group

**William Glomb, MD, FCCP, FAAP**

Senior Medical Director  
Superior HealthPlan

**Lindsay Botsford, MD**

Family physician  
Memorial Hermann Medical Group  
Medical Director of Physicians at Sugar Creek

**William Curry, MD**

Professor, Departments of Family and Community Medicine and Public Health Sciences  
Penn State College of Medicine

**Anna McCollister**

Co-Founder  
Galileo Analytics

**Ann E Kearns, MD, PhD**

Endocrinology Consultant  
Mayo Clinic

**Carlos Bagley, MD, FAANS**

Executive Vice Chair, Department of Neurosurgery Director  
UT Southwestern Spine Center

**James Mitchell Harris, PhD**

Director, Research and Statistics  
Children's Hospital Association (CHA)

**James Rosenzweig, MD**

Consultant in Endocrinology, Hebrew Rehabilitation Center Endocrinologist  
New England Allergy- Endocrinology

**Starlin Haydon-Greatting, MS-MPH, BSPHarm, CDM, FAPha**

Director of Clinical Programs & Population Health  
Illinois Diabetes Pharmacist Network

**Grace Lee, MD**

Section Head Endocrinology  
Virginia Mason Medical Center

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**Lorien Dalrymple, MD, MPH**

Vice President, Epidemiology & Research  
Fresenius Medical Care North America

**Renee Garrick, MD, FACP**

Professor of Clinical Medicine, Vice Dean, and Renal Section Chief  
Westchester Medical Center  
New York Medical College

**Alan Kliger, MD**

Clinical Professor of Medicine,  
Yale University School of Medicine Chair, Excellence in Patient Care Advisory Committee,  
American Society of Nephrology

PATIENT EXPERIENCE AND FUNCTION STANDING COMMITTEE MEMBERS

**Christopher Dezii, MBA, RN, CPHQ**

Former Lead, Healthcare Quality & Performance Measures  
Bristol-Myers Squibb Company Behavioral Health and Substance Use Standing Committee  
Members

**Brooke Parish, MD**

Executive Medical Director  
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