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National Consensus Development and Strategic Planning for Health Care Quality Measurement

Spring 2024 Cycle Endorsement and Maintenance (E&M) Meeting Discussion Guide

INITIAL RECOGNITION AND MANAGEMENT COMMITTEE

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Overview of Spring 2024 Measures for Review

For this measure review cycle, four measures were submitted to the Initial Recognition and Management committee for endorsement consideration (Table 1). The measures focused on malnutrition care during hospitalization, cardiovascular disease risk assessment for pregnant and postpartum patients, kidney health evaluation for diabetic patients, and pharmacotherapy for opioid use disorder (Figure 1).

Table 1. Overview of Measures Under Endorsement Review

CBE Number	Measure Title	New/Maintenance	Developer/Steward
3592e	Global Malnutrition Composite Score	Maintenance	Commission on Dietetic Registration
4360	CVD Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients Who Receive CVD Risk Assessment with a Standardized Tool	New	University of California, Irvine
4315e	Kidney Health Evaluation	New	National Kidney Foundation
3400	Use of Pharmacotherapy for Opioid Use Disorder	Maintenance	The Lewin Group/Centers for Medicare & Medicaid Services (CMS)

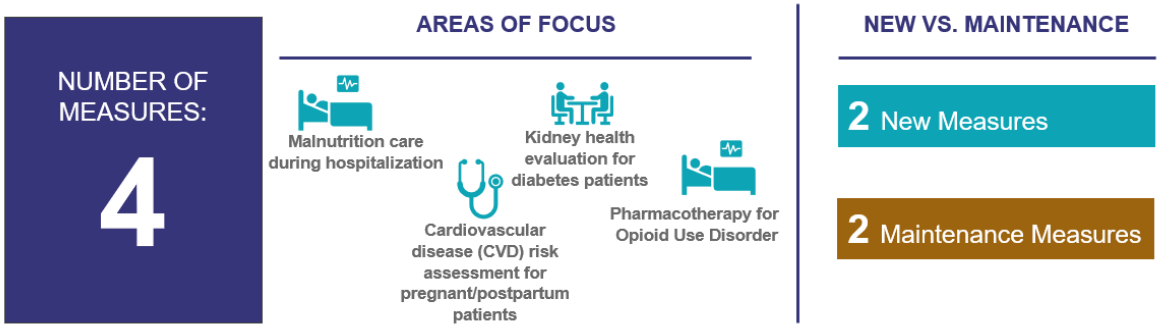

Figure 1. Spring 2024 Measures for Committee Review

Public Comment

Battelle accepts comments on measures under endorsement review through the Partnership for Quality Measurement (PQM) website and Public Comment Listening Sessions. For this evaluation cycle, the public comment period opened on May 16, 2024, and closed on June 14, 2024, and the Public Comment Listening Session was held on May 29, 2024.

Battelle received 65 public comments prior to the endorsement meeting. Sixty-two comments expressed support for CBE #3592e (one comment), CBE #4360 (59 comments), CBE #4315e (one comment), and CBE #3400 (one comment). The remaining three comments were non-supportive for CBE #4315e, expressing concern with reliability and providing recommendations on measure alignment and lowering the age limit in the specification.

After the public comment period closed, developers/stewards had the opportunity to submit written responses to the public comments received. Summaries of the public comments and developer/steward responses are provided within the respective measure evaluation summaries of this discussion guide below.

Advisory Group Feedback

The Advisory Group was convened on June 4, 2024. Fifteen of 22 (68%) active Advisory Group members were in attendance to share feedback and ask questions regarding the measures under endorsement review. Developers/stewards of the respective measures were also in attendance and provided responses to the Advisory Group discussions. After the meeting, developers/stewards had the opportunity to submit additional written responses to Advisory Group member feedback and questions.

Summaries of the Advisory Group member discussions and developer/steward responses are provided within the respective measure evaluation summaries of this discussion guide below.

To support the review of the public comments and Advisory Group summaries, the number of comments or individuals that shared similar comments, feedback, and/or questions is represented as “a few” (2-3 individuals), “several” (4-6 individuals), and “many” (more than 6 individuals).

Measures Under Endorsement Review

CBE #3592e: Global Malnutrition Composite Score [Commission on Dietetic Registration]

Measure Description: This composite measure assesses the percentage of hospitalizations for adults aged 18 years and older at the start of the inpatient encounter during the measurement period with a length of stay equal to or greater than 24 hours who received optimal malnutrition care during the current inpatient hospitalization where care performed was appropriate to the patient's level of malnutrition risk and severity. A version of this measure, assessing performance only for adults aged 65 years and older, is currently endorsed and active in the IQR program; this submission describes a substantive change in the measure, as the population is changed to all adults aged 18 and older.

Measure Status	
New or Maintenance: Maintenance	**Used in An Accountability Application?** Yes • Public Reporting • Regulatory and Accreditation Programs • Quality Improvement (Internal to the specific organization)
CBE Endorsement Status: Endorsed **Last Endorsement Review Cycle:** Fall 2020	**Proposed/Planned Use:** CMS Inpatient Quality Reporting Program

Measure Characteristics

Measure Type	Target Population(s)	Level of Analysis	Care Setting(s)
Composite	Adults: 18 and older	Facility	Hospital: Acute Care Facility, Critical Access, Inpatient

Measure Overview
Rationale: Malnutrition is a leading cause of United States (U.S.) morbidity and mortality. Evidence suggests that 20% to 50% of all patients are malnourished or at risk of malnutrition at the time of hospital admission, with up to 31% of these malnourished patients and 38% of well-nourished patients experiencing nutritional decline during their hospital stays. Insufficiency of available nutrients needed to promote healing and rehabilitation may lead to an increased risk of medical complications, including depression of the immune system, impaired wound healing, muscle wasting, and increased mortality. Malnutrition and weight loss can also contribute to sarcopenia, or a loss of skeletal muscle mass and function, which also impedes an individual's recovery, mobility, ability to perform daily activities, and independence.
Numerator: This is a continuous variable measure. "Measure Observation 1" = "Encounters with Malnutrition Risk Screening and Identified Result"; "Measure Observation 1" identifies hospital encounters where a "Malnutrition Risk Screening" was

Measure Overview
performed with a current identified "Malnutrition Screening Finding of Not At Risk Result" or current "Malnutrition Screening Finding of At Risk Result" OR a "Hospital Dietitian Referral" was ordered. "Measure Observation 2" = "Encounter with Nutrition Assessment and Identified Status"; "Measure Observation 2" identifies hospital encounters where a "Nutrition Assessment" was performed with a current identified "Nutrition Assessment Status Finding of Well Nourished or Not Malnourished or Mildly Malnourished", "Nutrition Assessment Status Finding of Moderately Malnourished", or "Nutrition Assessment Status Finding of Severely Malnourished." "Measure Observation 3" = "Encounters with Malnutrition Diagnosis"; "Measure Observation 3" identifies hospital encounters where a current "Malnutrition Diagnosis" was documented. “Measure Observation 4” = “Encounters with Nutrition Care Plan”; "Measure Observation 4" identifies hospital encounters where a current "Nutrition Care Plan" was performed. "Population 5 Measure Observation TotalMalnutritionComponentsScore" equals the sum of ("Measure Observation 1" plus "Measure Observation 2" plus "Measure Observation 3" plus "Measure Observation 4"). "Population 6 Measure Observation TotalMalnutritionCompositeScore as Percentage" = 100 * ("TotalMalnutritionComponentsScore" divided by "TotalMalnutritionCompositeScore Eligible Denominators"). -For each hospitalization, Population Criteria 6 represents the sum of performed Measure Observations 1, 2, 3, and 4 divided by the number of clinically eligible occurrences.
Denominator: TotalMalnutritionCompositeScore Eligible Occurrences" is 4 except in the following instances: • If a "Malnutrition Risk Screening" was performed and a "Malnutrition Screening Finding of Not At Risk Result" was identified AND "Hospital Dietitian Referral" was not ordered, then the "TotalMalnutritionCompositeScore Eligible Occurrences" is 1. • If a "Malnutrition Risk Screening" was performed OR a "Hospital Dietitian Referral" was ordered AND a "Nutrition Status Finding of Well Nourished or Not Malnourished or Mildly Malnourished" was identified OR a Nutrition Assessment was not completed, then the “TotalMalnutritionCompositeScore Eligible Occurrences” are 2. • For the reporting facility, the Population Criteria 6 averages the performance of each "TotalMalnutritionCompositeScore as Percentage" across all eligible hospitalizations during the measurement period.
Exclusions: None
Measure is Risk-Adjusted and/or Stratified: No risk adjustment or stratification.

Logic Model
Summary: Early hospital-based malnutrition identification and documentation allows care teams to address a patient’s condition with an appropriate plan of care and communicate patient needs to other care providers. The process for risk identification, assessment, diagnosis, and treatment of malnutrition necessitates a multi-disciplinary care team that begins with the identification of an initial risk population for a more thorough physical assessment by registered dietitian (RD) or registered dietitian nutritionists (RDN). For patients identified with a moderate or severe malnutrition status from the nutrition

Logic Model
assessment, best practice also recommends a medical diagnosis by a physician or other qualified healthcare professional and the execution of the nutrition care plan by an RD/RDN. Evidence demonstrates that implementing a standardized protocol for screening, assessment, diagnosis, and care planning results in better identification of malnourished patients and subsequent improvements in rates of nutrition intervention for the malnourished. The measure developer provided a clinical workflow in which, after an adult patient is admitted to the hospital, they have a nutrition risk screening and/or a referral to a hospital dietitian. Based upon their level of risk or if they have a referral to a dietician, a nutrition assessment is completed. Depending on the level of malnutrition that is identified a nutrition care plan or a medical diagnosis is completed and/or added to their care plan. After assessment, a patient is discharged to the community with a referral to supporting community resources or recommendations for post-acute care.

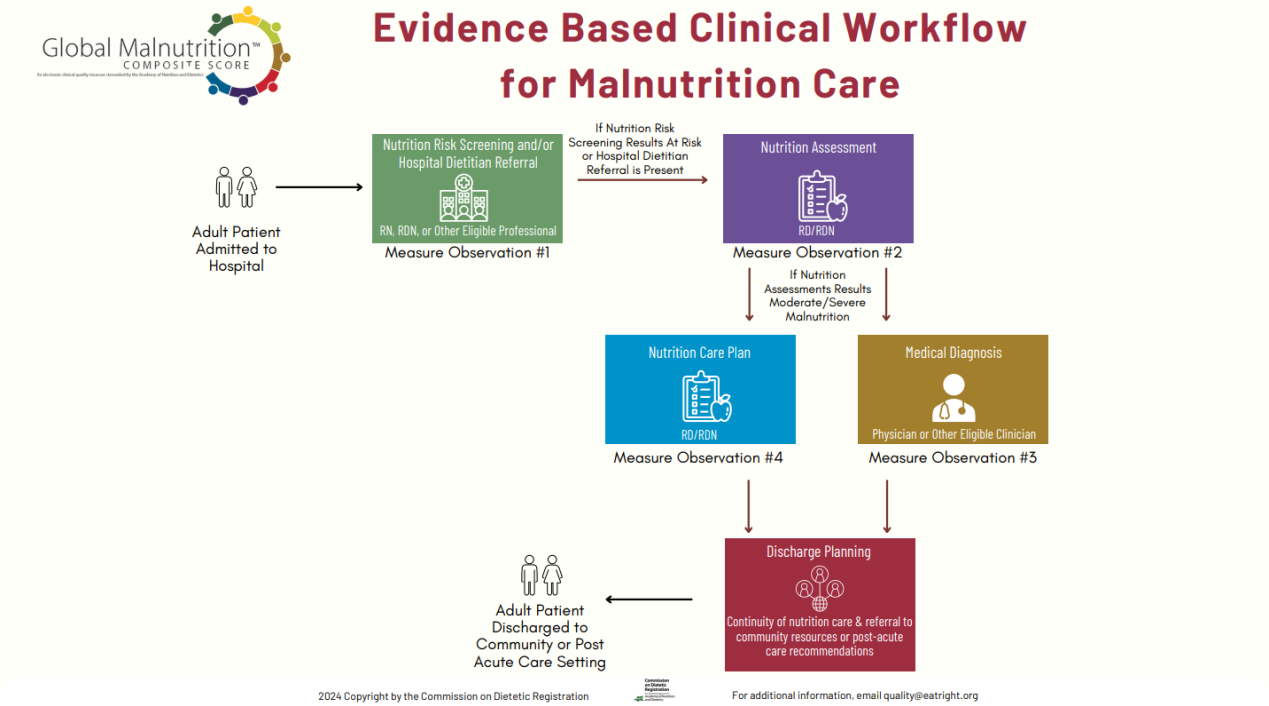

Figure 2. CBE #3592e Logic Model

Measure Evaluation Summary: CBE #3592e

Importance
Staff Preliminary Rating: Not met but addressable
Importance: There is a business case for the measure with some supporting evidence. More recent evidence showing the importance of the measure to patients should be considered.

Feasibility
Staff Preliminary Rating: Not met but addressable
Feasibility: The developer conducted a feasibility assessment across three hospital systems representing two electronic health record vendors, Epic and Meditech. The developer identified some issues with data element availability, accuracy, and standards at one of the three hospital systems, but explained these issues would be resolved with measure implementation. The developer does not indicate in their feasibility assessment whether all required data elements used to calculate this measure are routinely generated and used during care delivery.

Reliability	
Staff Preliminary Rating: Met	
Testing Level:	Accountable Entity Level and Person or Encounter Level
Testing Method:	Reliability testing was conducted using **signal-to-noise** and **test-retest reliability methods**. The signal-to-noise reliability ranged from 0.69 to 1.00 with a **median of 0.99.** For test-retest, **Spearman's correlation averaged at 0.97** and ranged from 0.91 to 0.99, and the **ICC averaged at 0.96** and ranged from 0.83 to 0.99.
Reliability: The measure is well-defined. Reliability was assessed at both the patient and entity level. Reliability statistics are above the established thresholds.	

Validity	
Staff Preliminary Rating: Met	
Testing Level:	Accountable Entity Level and Person or Encounter Level
Testing Conducted:	**Empirical validity testing** was conducted by **using a two-step analysis** to assess whether the measure relates to various malnutrition-associated factors. As hypothesized, the developer **found significant differences in measure scores across readmission status and race/ethnicity factors**. Unexpectedly, the developer **did not find significant differences in measure scores across age or length of stay** but explained this may be due to the relatively small sample size of facilities. The developer conducted **data element-level validity testing** and found

Validity	
	100% agreement on all tested data elements. The developer also conducted **face validity,** and **73.9%** of clinicians agreed or strongly agreed that the measure can be used to distinguish good from poor quality of care.
Validity: The developer assessed measure validity using accountable entity-level empirical validity, data element-level validity, and face validity. The interpretation of the empirical results supports an inference of validity.	

Equity	
Staff Preliminary Rating: Met	
Equity considered:	Yes
Equity: The developer evaluated disparities in performance by race/ethnicity. The developer assessed how the measure contributed to efforts to address inequities in health care.	

Use & Usability	
Staff Preliminary Rating: Not met but addressable	
Current or Planned Use:	CMS Hospital Inpatient Quality Reporting Program
Use & Usability: The measure is currently used in the Hospital IQR Program. The developer describes actions measured entities can take to improve performance on each component if the observation has a low score. The developer did not report any findings on the progress on improvement as data from measure reporting are not yet available.	

Public Comment[1]

Number of Comments Received: 1

Full text of developer/steward responses can be found on the PQM website.

Comment Summary	Support Level	Summary of Developer Response
One comment was supportive that the developer had changed the age to 18 and above. Before, this measure did not incorporate individuals with digestive disease or eating disorders.	Supportive	• Significant discrepancies exist between estimated rates of malnutrition and coded diagnoses. • The Global Malnutrition Composite Score measure (GMCS) follows the evidence- and consensus-based Nutrition Care Process, well-established in many acute care facilities.

[1] Comments, as submitted, can be found on the PQM website.

Comment Summary	Support Level	Summary of Developer Response
		• Evaluation of malnutrition care across the age spectrum is critical to improving outcomes.

Advisory Group Feedback

Full text of developer/steward responses can be found on the PQM website.

Feedback/Questions	Summary of Developer Response
Potential Burden on Hospital Systems: A committee member asked: What are the screening requirements, are they standard, and will this be a potential burden on hospital systems?	A malnutrition risk screening is standard and is a requirement of The Joint Commission. For this measure, hospitals pick a screening tool that is feasible and accessible to them, so the measure should not impart additional burden. A full nutrition assessment should then occur prior to discharge if a patient is identified to be at risk of malnutrition. *Summary Response Received after the Advisory Group meeting:* • A valid and reliable malnutrition screening tool is recommended, though not required. • Current Joint Commission standards require completion of nutrition screening during acute care encounters, minimizing implementer burden. • GMCS is a self-selected measure.
Definition of "Malnutrition:" A committee member asked: Are overnutrition and undernutrition included in how "malnutrition" is defined in the measure? The committee members noted that the World Health Organization defines malnutrition as overnutrition and undernutrition and recommended being consistent with international standards.	The measure does not address overnutrition. The developer said that they have found that if they state items such as overnutrition, providers tend to exclude anyone with a body mass index (BMI) of more than 25. The developer may explore language about how nutrition issues can occur at any BMI. *Summary Response Received after the Advisory Group meeting:* • The generally accepted definition of malnutrition recognizes that it may occur at any weight/BMI. • Malnutrition is characterized by a constellation of symptoms, including but not limited to weight change, low/high BMI, chronic disease, increased metabolic requirements, altered diets, and inadequate intake. • An individual with only a high BMI and no other malnutrition-specific findings will not be included in performance measurement.

Feedback/Questions	Summary of Developer Response
Impact on Rural and Critical Access Hospitals: A committee member asked: What impact does this measure have on rural or critical access hospitals, which may not have as much nutrition or dietary resource support?	The developer acknowledged the limitations of availability of dietitians. They stated that this is why the measure has no time parameters, so providers may have freedom to match standard timelines. They added that rural dietitians have also started to complete the assessments remotely. *Summary Response Received after the Advisory Group meeting:* • GMCS is a self-selected measure. • No timing element. • Individuals of interest for this measure are hospitalized adults with moderate or severe malnutrition, independent of their BMI.
Measure Performance: A committee member asked: Has the current measure seen any movement in performance? Do you have any data on how many hospitals have selected to report on this measure? Another committee member commented on the range of performance across the testing sites being narrow. They asked whether those 28 facilities are topped-out. And is this reflective of what might be expected nationally?	The current measure is still in its first year of reporting, so there are no reported results to date. The developer, however, has continued to update the measure logic to ease burden. They noted they also do not have data on which hospitals have selected to report on this measure at this time. The testing sites were extremely engaged hospitals that the developer classified as the gold standard. Their performance is above what the developer would expect in a traditional day-to-day facility. The developer does not expect the measure to be topped-out. *Summary Response Received after the Advisory Group meeting:* • The facilities utilized for data analysis are exceptionally high performing. • Topped-out analysis reveals the GMCS is not topped out. • While Measure Observation (MO) 1 may present with higher scores, the remaining components—MO2, MO3, and MO4—display notable variations, suggesting substantial potential for enhancement.
Unintended Consequences: A committee member commented that malnutrition is a condition that is heavily denied by the Office of General Inspector (OGI) and insurance companies. They asked whether there would be an increase in denials and costs incurred by the hospital. What other unintended consequences might there be even if the measure is clinically good?	The developer said they were aware of the OGI's concerns; a primary issue is that facilities were often using tools that were not valid and reliable. The developer said they recommend using tools that are valid and reliable to ensure the diagnosis is accurate.

Feedback/Questions	Summary of Developer Response
	The presence of malnutrition can impact reimbursement, but the developer sees this as a potential positive for facilities. If malnutrition becomes an important and visible topic within multiple disciplines, diagnoses may become more accurate and reliable. *Summary Response Received after the Advisory Group meeting:* • OIG denials for severe malnutrition coding were primarily due to clinicians using nutrition assessment tools that were not valid and reliable and/or documentation lacked a clear care plan associated with the diagnosis. • The GMCS recommends use of valid and reliable assessment tools and evidence-based processes that include supportive evidence for the diagnosis. • Electronic Clinical Quality Measure (eCQM) implementation efforts often result in accompanying improvements in and standardization of care, which is likely to improve accuracy of malnutrition diagnoses.
Redundancy: Due to The Joint Commission's recommendation that a malnutrition screening be standard, a committee member asked whether the measure is redundant.	Compliance with The Joint Commission's recommendation is not 100%. The measure only targets patients who are at risk of malnutrition. *Summary Response Received after the Advisory Group meeting:* • Despite being a Joint Commission standard, a documented performance gap still exists in rates of malnutrition risk screening. • Screening serves as the entry point to the Nutrition Care Process. • The GMCS includes additional steps, once malnutrition risk is identified, that support improved patient outcomes.
Hospice Patients: A committee member asked whether there are any considerations for patients who are in hospice.	The developer noted that they frequently receive this question. They said they recommend following hospital policy. If a hospice patient is identified and it is noted that an aggressive intervention is not appropriate at the time, the measure is listed as complete. *Summary Response Received after the Advisory Group meeting:* • GMCS focuses on identifying and addressing malnutrition, regardless of hospice status.

Feedback/Questions	Summary of Developer Response
	• Nutrition interventions and associated care plans encourage patient autonomy, which may include limited nutrition interventions aligned with goals of care.
Validity Testing: A committee member asked for the developer to provide an overview of the analysis performed.	In the empirical validity testing, the developer said they included the expected outcomes of those with malnutrition risk versus those without. They found that patients with malnutrition who are in facilities doing well will have higher scores. They sought to find patients with typical markers of being more at risk. They looked at older patients, length of stay, race, and readmission. *Summary Response Received after the Advisory Group meeting:* • Validity testing found significant differences in the malnutrition screening result across all four patient and encounter characteristics: namely, that encounters of older patients had more "at-risk" results than younger patients, longer stays more than shorter stays, readmission encounters more than non-readmissions, and encounters of non-Hispanic Black patients more than non-Hispanic white patients. • We also found significant differences in facilities' GMCS measure scores across the readmission status and race/ethnicity factors, where the GMCS among readmission encounters were lower than that of non-readmission encounters, and the GMCS among encounters of non-Hispanic Black patients were lower than that of non-Hispanic white patients. • Data element validity results demonstrate no variation in the validity or the data elements by sites, with all sites reporting 100% agreement on all tested data elements. • Face validity, conducted through a web survey, revealed overall support among clinicians, with most agreeing or strongly agreeing that the GMCS is an accurate reflection of malnutrition care quality, and that it can be used to distinguish between good and poor quality of malnutrition care .

Key Discussion Points:

- **Importance:** The cited 2011 clinical practice guidelines from American Society for Parenteral and Enteral Nutrition have moderate to low grading and more recent evidence showing the importance of the measure to patients should be considered.

    - The developer noted the measure also follows the Nutrition Care Process (NCP), an evidence- and consensus-based quality improvement process designed to standardize terminology and improve consistency in malnutrition care. Additionally, 2023 input from the technical expert panel, which contains representation from patients and patient advocates, included strong support of measure population expansion to include all adults aged 18 and older.
- **Feasibility:** Does the committee have concerns about feasibility issues due to data element value sets not being coded?
    - The developer explained the data elements needed for the measure are part of the current standardized workflow at the three hospital systems that participated in feasibility testing, and efforts are in place to document each component in discrete fields. Facilities reported that few of these data elements were mapped to associated codes/value sets for eCQM reporting because, outside of malnutrition diagnosis, prior nutrition-specific mapping was not clinically nor operationally indicated.
- **Measure Performance:** Range of performance across the testing sites was narrow.
    - The developer noted that test sites were extremely engaged hospitals and their performance is above what the developer would expect in a traditional day-to-day facility. The developer conducted a topped-out analysis that revealed the GMCS is not topped-out and while Measure Observation (MO) 1 may present with higher scores, the remaining components—MO2, MO3, and MO4—display notable variations, suggesting substantial potential for enhancement.
- **Use and Usability:** Improvement data from measure reporting are not yet available.
    - The developer indicated that calendar year 2024 offers the first opportunity for facilities to collect and report Global Malnutrition Composite Score (GMCS) data on older adults.

CBE 4360: CVD Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients Who Receive CVD Risk Assessment with a Standardized Tool [University of California, Irvine]

Measure Description: This measure determines the percentage of pregnant or postpartum patients at a given clinic who were assessed for cardiovascular disease (CVD) risk with a standardized tool, such as the CVD risk assessment algorithm developed by the California Maternal Quality Care Collaborative (CMQCC). The aim is to perform CVD risk assessment using a standardized tool on all (100%) eligible pregnant/postpartum patients.

Measure Status	
New or Maintenance: New	**Used in An Accountability Application?** Yes • Payment Program • Quality Improvement with Benchmarking (external benchmarking to multiple organizations) • Other
CBE Endorsement Status: N/A **Last Endorsement Review Cycle:** N/A	**Proposed/Planned Use:** 2024 CMS Merit-based Incentive Payment (MIPS) Value Pathways (MVPs)

Measure Characteristics

Measure Type	Target Population(s)	Level of Analysis	Care Setting(s)
Process	Patients receiving prenatal care and postpartum care at a health care facility	Clinician: Group/Practice, Clinician: Individual	Birthing Center, Clinician Office/Clinic, Emergency Department, Hospital: Inpatient, Hospital: Outpatient, Urgent Care - Ambulatory

Measure Overview
Rationale: Cardiovascular disease (CVD) is a leading cause of maternal mortality in the United States, responsible for over one-third of pregnancy-related deaths. Misdiagnosis of CVD is expected due to similar symptoms caused by pregnancy. Hence, it is crucial to identify pregnant and postpartum people at risk for CVD disease and/or with previously unknown CVD with a standardized risk assessment. Monitoring of these patients and timely interventions contribute to the prevention and mitigation of CVD-related complications and mortality. The proposed measure will allow clinicians to gauge the extent to which they use a standardized tool in their clinic practice and inform interventions to encourage its use.
Numerator: The percentage of all pregnant and postpartum patients who received a CVD risk assessment with a standardized tool.

Measure Overview
Denominator: All patients receiving prenatal care and postpartum care at a given clinic, hospital, healthcare network, or private practice (group B "Pregnant and Postpartum Office Visit" in the CPT-ICD 10 Code Book). Any person who is receiving antepartum or postpartum care in a healthcare system should undergo risk assessment.
Exclusions: Patients who have a reason other than ongoing pregnancy care for visiting the clinic (Group C).
Measure is Risk-Adjusted and/or Stratified: No risk adjustment or stratification.

Logic Model
Summary: The measure developer has identified that by strategically intervening by screening postpartum women for cardiovascular disease risk that it will lead to better pregnancy outcomes. By increasing rates of screening, it should lead to a larger number of follow-up tests, or appropriate follow-up care. This should lead to immediate health outcomes of clinician adherence to clinical guidelines and the role of cardiovascular health during pregnancy and postpartum. It should also lead to increased patient awareness of cardiovascular risk and in turn decrease in risky behaviors. Long-term outcomes should include a decreased in risky patient behaviors which can lead to hospital admissions, and improved maternal and infant health outcomes.

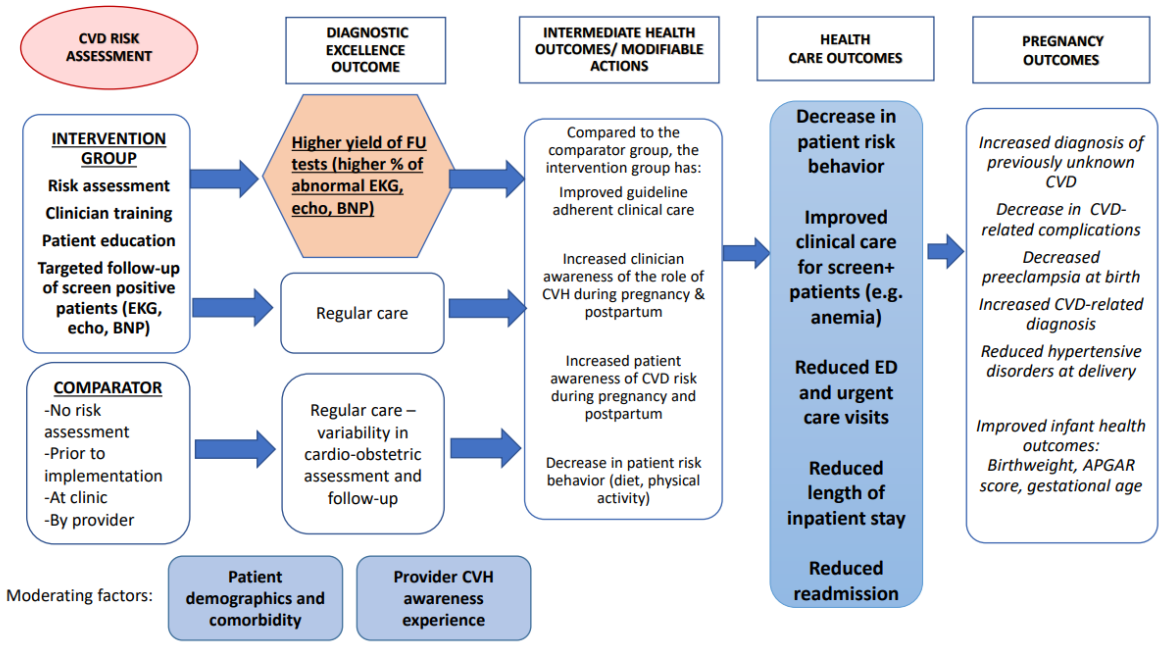

Figure 3. CBE #4360 Logic Model

Measure Evaluation Summary: CBE #4360

Importance
Staff Preliminary Rating: Met
Importance: The measure focus is well supported by empirical data from prenatal and postpartum populations, and similar assessments have been endorsed by clinician groups, including American College of Obstetricians and Gynecologists (ACOG). CVD is the leading cause of maternal mortality and many of these cases are preventable. The developers do a thorough job of evaluating the importance of this measure focus to patients and expanded their technical expert panel (TEP) to include patients with experience with CVD. In addition, the evidence base shows disparities in maternal mortality and post-delivery complications. The developer indicates that a measure assessing clinician performance in this area is lacking. It would be helpful to know what resources they reviewed before drawing this conclusion.

Feasibility
Staff Preliminary Rating: Met
Feasibility: The measure includes an algorithm to be integrated into electronic health records (EHRs), and once this is done, the measure is easily generated, assuming clinicians receive appropriate training in using the assessment. While this is not categorized as an eCQM, the committee could consider whether this submission would benefit from more information regarding completeness of the data elements across EHR systems, and if the implementation guide is sufficient. The developer does not describe any feasibility assessment performed for the paper option. The measure contains some proprietary code but there are no fees associated with the measure.

Reliability	
Staff Preliminary Rating: Met	
Testing Level:	Accountable Entity Level
Testing Method:	Reliability testing was conducted using **signal-to-noise,** and results reported showed a range from 0.839 to 1.0 with a **median of 0.992**.
Reliability: The measure is well-defined. Reliability was assessed at the entity level. Reliability statistics are above the established thresholds for all entities.	

Validity	
Staff Preliminary Rating: Met	
Testing Level:	Accountable Entity Level
Testing Conducted:	**Empirical validity** and **face validity** testing were conducted (more information on results included below).
Validity: The developer conducted empirical accountable entity-level validity testing by calculating the correlation between the measure score and percentage of confirmed CVD cases in a cohort of 10,860 patients. The developers hypothesized and observed a positive correlation with a resulting Pearson Correlation Coefficient of r=0.424. The developer observed that patients with a positive risk assessment result were	

Validity
significantly more likely to have an abnormal follow-up test result than those with a negative result. The developer also collected face validity feedback from a TEP, 100% of which agreed that the measure is consistent with CVD diagnosis. The developer reported high (100%) face validity but provided no details regarding how this was assessed. No data element testing was reported for this new measure. While this criterion is scored as 'Met', the committee should consider requesting more information regarding the establishment of face validity for this measure. In addition, the committee should explore whether the performance characteristics of the instrument have been sufficiently evaluated.

Equity	
Staff Preliminary Rating: Not met but addressable	
Equity considered:	Yes
Equity: For this new measure, the developer cites empirical research that establishes disparities by race in maternal morbidity and mortality, including CVD. The developer did not report whether they explored potential disparities in their testing data.	

Use & Usability	
Staff Preliminary Rating: Met	
Current or Planned Use:	2024 CMS Merit-based Incentive Payment (MIPS) Value Pathways (MVPs)
Use & Usability: The developer reports that the measure is currently used in the 2024 MIPS MVPs. The developer lists actions entities can take to improve performance, including identifying clinics or clinicians who underperform, prioritizing clinician training, integrating training into onboarding residents and new hires, and mentoring from experienced clinicians. The committee should consider whether there is a system for collecting and acting on feedback about the measure and if there have been any unintended consequences with its use.	

Public Comment[2]

Number of Comments Received: 61

Full text of developer/steward responses can be found on the PQM website.

Comment Summary	Support Level	Summary of Developer Response
Fifty-nine comments expressed support for the measure. Many health care professionals, organizations, and patient advocacy groups strongly support the implementation of the CVD risk assessment tool developed by UCI. They recognize its potential to	Supportive	Thank you for your support and commitment to improving maternal health outcomes. We greatly appreciate your dedication to this important cause.

[2] Comments, as submitted, can be found on the PQM website.

Comment Summary	Support Level	Summary of Developer Response
significantly reduce maternal mortality and improve health care quality by identifying high-risk cardiovascular conditions in pregnant and postpartum patients.		
Of those 59 commenters, 46 mentioned the importance of early detection and management: Commenters emphasize the importance of early detection and management of CVD risk factors, which can lead to timely and effective interventions, reducing the number of adverse pregnancy events and lowering health care costs.	Supportive	Thank you for your support and commitment to improving maternal health outcomes. We greatly appreciate your dedication to this important cause.
Of those 59 commenters, 33 mentioned the integration into EHR systems: The integration of this tool into EHR systems is highlighted as a critical factor that streamlines the process, ensuring comprehensive screening and better patient outcomes.	Supportive	Thank you for your strong endorsement of our CVD Risk tool developed by University of California, Irvine (UCI). We are thrilled to hear that you support its implementation and recognize its potential to significantly improve maternal health outcomes. Your feedback on the tool's integration into the EHR system and its role in enhancing diagnostic accuracy is greatly appreciated. We share your belief that early identification and management of CVD risk factors will lead to better patient outcomes and reduced health care costs. Thank you for your valuable support in the fight against maternal mortality.
One commenter asked for clarification on whether the measure is based on clinical guidelines that would outline how frequently the assessment should occur. They further stated they were unable to determine a performance gap and if the level of testing performed aligns with the levels of analysis.	N/A	Thank you for your unwavering support and commitment to reducing maternal morbidity and mortality. We deeply appreciate your advocacy for this critical measure. We share your commitment to ensuring that this measure is based on rigorous clinical guidelines, particularly concerning the frequency of assessments for cardiovascular disease during pregnancy. Your points about clarifying the performance gap and aligning testing levels with clinician analysis are crucial for optimizing maternal care and are noted.
One commenter supports allowing those implementing the measure to modify the California Maternal Quality Care Collaborative risk assessment tool with additional data on CVD risk assessment or using an alternative method when available. The same commenter noted that the CQMCC tool includes African American race as a variable, which is a proxy for implicit bias rather than a biological variable.	N/A	Thank you for your support of our proposed CVD risk assessment measure for pregnant and postpartum patients. We appreciate your recognition of its importance in improving patient outcomes and your endorsement of the CMQCC tool. Your insights on ensuring flexibility and addressing implicit bias are invaluable. We are hopeful that with your support, our measure will be endorsed and integrated into standardized care, helping to reduce CVD-related risks for all patients.

Advisory Group Feedback

Full text of developer/steward responses can be found on the PQM website.

Feedback/Questions	Summary of Developer Response
Patient Population: A committee member asked for more rationale regarding the specific patient population included in the measure. Would the tool be better served as part of an annual physical, so all women are being screened?	Cardiovascular (CV) screening tools already exist for non-pregnant patients. In the U.S., CV is the No. 1 cause of maternal mortality. The developer said they are seeking to impact the maternal mortality rate, adding that about 1/3 of the pregnant/postpartum individuals who died as a result of cardiovascular disease (CVD) would have survived if they had been identified. They added that it is common for vital sign abnormalities not to be recognized as CVD in pregnant and postpartum patients. The algorithm puts everything together to identify those who are at increased risk, get a diagnosis, and then treatment. The developer added that pregnancy is an especially important time because the body is under additional stressors and the patient is routinely receiving health care. *Summary Response Received after the Advisory Group meeting:* • We focus on screening during pregnancy and postpartum due to CVD being the leading cause of preventable maternal mortality. • Pregnancy serves as a stress test, with cardiac symptoms often overlooked or disregarded. • A structured CVD risk assessment tool at the first obstetrics visit is crucial for early detection, aligning with literature that shows improved outcomes with early diagnosis and treatment.
Feasibility: A few committee members asked how easy it would be to implement this tool into an electronic health record (EHR) system. A committee member also expressed concern that "care systems" was defined too broadly. The member recommends that it may be more appropriate to build this into the workflows of obstetricians and birthing centers.	The developer said they have the tool built into their EHR system, that it is an easy tool to teach, and that the nurses do the preliminary screening and screen 700 to 800 patients per month. They use Epic and have shared their build in Epic with many other institutions. Most of the data is auto-populated. The developer said they include primary care and the emergency department in the measure because 1/3 of CV occurrences are after delivery, which may occur outside of the timeframe for obstetric (OB) care. *Summary Response Received after the Advisory Group meeting:*

Feedback/Questions	Summary of Developer Response
	• The CVD Risk Assessment Tool has been successfully implemented in various institutions that serve prenatal and postpartum patients using two of the most commonly used electronic medical record (EMR) systems, EPIC and Cerner. • It takes about 20 hours of information technology (IT) time to develop and integrate the tool into various EMRs. • Although integration into EHR systems requires an IT investment, the time required is comparable to other EHR system changes; and this burden should be weighed against the immense potential benefit to patients that has been quantified and discussed elsewhere. • The proposed measure is intended for use during the pregnancy episode limited to visits for direct obstetrical care.
Timeframe: A committee member asked about when the risk assessment needs to happen during the prenatal/postpartum period.	The developer said they recommend a patient be screened during pregnancy once and, if they have symptoms, then be screened again. *Summary Response Received after the Advisory Group meeting:* • Risk assessment at least once during pregnancy, ideally at the first visit, enables early detection of previously unknown CVD risk and CVD. • Repeat risk assessment may be indicated if symptoms suspicious for CVD develop. • We are currently evaluating the predictive value and optimal timing of repeat risk assessments for detection of CVD.
Attribution: A committee member asked about attribution. If a patient is at a routine appointment for an unrelated matter, such as a dermatology appointment, and they select that they are pregnant, is that provider then responsible for an assessment?	The developer clarified that routine and unrelated visits are not included in the denominator. The tool is linked to the pregnancy episode. *Summary Response Received after the Advisory Group meeting:* • Include all patients receiving prenatal and postpartum care in the denominator for risk assessment. • Patients visiting for reasons other than prenatal or postpartum care are excluded from the denominator.
Unintended Consequences: A committee member asked about a potential unintended consequence related to the measure. They noted that there's a larger issue with maternity care deserts, where providers, particularly critical access and rural hospitals, are saying that pregnancy care is too risky and has too many factors with which	The developer responded that this is part of why primary care and emergency departments are included as part of the measure. They added that remote areas can complete a checklist on paper and that there is a role for telemedicine.

Feedback/Questions	Summary of Developer Response
to deal. Will this measure contribute to the complexity and result in providers being unwilling to take care of these patients?	*Summary Response Received after the Advisory Group meeting:* • Integrating CVD risk assessment into routine obstetric care is proactive, enabling early identification, triage, transport, and timely treatment, which may be of particular value in remote areas and maternity care deserts. • This measure helps prevent perinatal emergencies by identifying in advance those patients who may need specialized care, making pregnancy care more manageable. • Our implementation work group is committed to supporting providers with best practices, remote technical assistance, and streamlined protocols to ensure smooth implementation and minimize the burden on health care providers.
Postpartum Definition: A committee member asked how the measure defines "postpartum?"	The developer did not respond to this feedback/question during the meeting. *Summary Response Received after the Advisory Group meeting:* • Postpartum is the time after delivery until the provider closes the pregnancy episode in the patient's medical record.
Next Steps After Screening: A committee member raised a question about next steps, asking if patient is screened and found to be at risk, what does the measure then recommend?	The developer did not respond to this feedback/question during the meeting. *Summary Response Received after the Advisory Group meeting:* • If a patient is determined to be at risk for CVD after completion of the CVD Risk Assessment, a smart order set with recommended follow-up tests appears in the EMR. The health care provider can choose cardiac testing and follow up based on available resources and at the discretion of the health care provider.
Rescreening: A committee member asked what prevents a patient from being screened again and again, resulting a large burden for the provider?	The developer said they recommend a patient be screened during pregnancy once and, if they have symptoms, then be screened again. They added that the EHR system relays one flag per pregnancy episode and once the patient is screened, the flag goes away. *Summary Response Received after the Advisory Group meeting:*

Feedback/Questions	Summary of Developer Response
	• A banner alerts providers to complete the CVD Risk Assessment once a pregnancy episode is initiated in the EHR. • The banner changes colors after the risk assessment is completed, preventing unnecessary screening. • Institutions without an EMR may establish an alternate process based on their resources.

Key Discussion Points:

- **General Support/Importance:** Many health care professionals, organizations, and patient advocacy groups indicated strong support: maternal mortality rates are an important issue with a large gap.
- **Feasibility:** Checklist can be completed on paper. Was feasibility evaluated for this option?
- **EHR Integration:** Does the committee have concerns about barriers to implementing the tool into EHR systems, even if a build is available?
    - The developer noted the CVD Risk Assessment Tool has been successfully implemented in various institutions, including two of the most used EMR systems (Epic and Cerner) and it takes about 20 hours of IT time to develop and integrate into EMRs. Although integration into EHR systems requires an IT investment, the time required is comparable to other EHR system changes, and this burden should be weighed against the immense potential benefit to patients.
- **Rescreening:** Does the committee have concerns about unnecessary or repetitive screenings?
    - The developer noted the proposed measure is intended for use during the pregnancy episode, limited to visits for direct obstetrical care. A banner alerts providers to complete the CVD Risk Assessment once a pregnancy episode is initiated in the electronic record. The banner changes colors after the risk assessment is completed, preventing unnecessary screening. Institutions without an EMR may establish an alternate process based on their resources.
- **Use/Usability:** The committee should consider whether there is a system for collecting and acting on feedback about the measure and if there have been any unintended consequences with its use.

CBE 4315e: Kidney Health Evaluation [National Kidney Foundation]

Measure Description:

Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.

Measure Status	
New or Maintenance: New	**Used in An Accountability Application?** Yes • Payment Program
CBE Endorsement Status: N/A **Last Endorsement Review Cycle:** N/A	**Proposed/Planned Use:** Center for Medicare & Medicaid Services (CMS) Merit-Based Incentive Payment System (MIPS)

Measure Characteristics

Measure Type	Target Population(s)	Level of Analysis	Care Setting(s)
Process	Adults and elderly aged 18-85 years	Clinician: Individual	Clinician Office/Clinic

Measure Overview
Rationale: Chronic Kidney Disease (CKD) is a major driver of morbidity, mortality and high healthcare costs in the United States. Currently, 37 million American adults have CKD and millions of others are at increased risk (National Kidney Foundation [NKF], 2022), with an estimated population prevalence growing to nearly 17% among Americans aged 30 years and older by the year 2030 (Saran et al., 2019; Hoerger et al., 2015). Total Medicare spending in 2016 on both CKD and End-Stage Renal Disease (ESRD) was over $114 billion, comprising 23% of total Medicare fee-for-service spending overall with costs increasing exponentially with advancing CKD (Saran et al., 2019; Nichols et al., 2020). In the US from 2002-2016, the burden of CKD, defined as years of life lost, years living with disability, disability-adjusted life years, and deaths, outpaced changes in the burden of disease for other conditions (Bowe et al., 2018). Patients with CKD are readmitted to the hospital more frequently than those without diagnosed CKD (Saran et al., 2019). CKD is the 9th leading cause of death in the US and is the fastest growing non-communicable disease in terms of in burden largely due to death (Hoerger et al., 2015; Bowe et al., 2018). This public health issue is driven largely by the impact of diabetes—the most common comorbid risk factor for CKD (Saran et al., 2019; Bowe et al., 2018).
Numerator: Patients who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the 12-month measurement period.
Denominator: All patients aged 18-85 years with a diagnosis of diabetes with at least one visit during the measurement period.
Exclusions: Patients with a diagnosis of ESRD active during the measurement period. Patients with a diagnosis of CKD Stage 5 active during the measurement period. Patients who have an order for or are receiving hospice or palliative care.
Measure is Risk-Adjusted and/or Stratified: No risk adjustment or stratification.

Logic Model
Summary: Patients with a diagnosis of diabetes are at increased risk of developing CKD and an annual kidney health evaluation using eGFR and uACR allows clinicians to identify and potentially treat or delay its progression. In addition, by increasing performance on these tests it will address the issues of under-recognition and under-diagnosis, as many patients are not aware of their own kidney health status and/or a diagnosis of CKD.

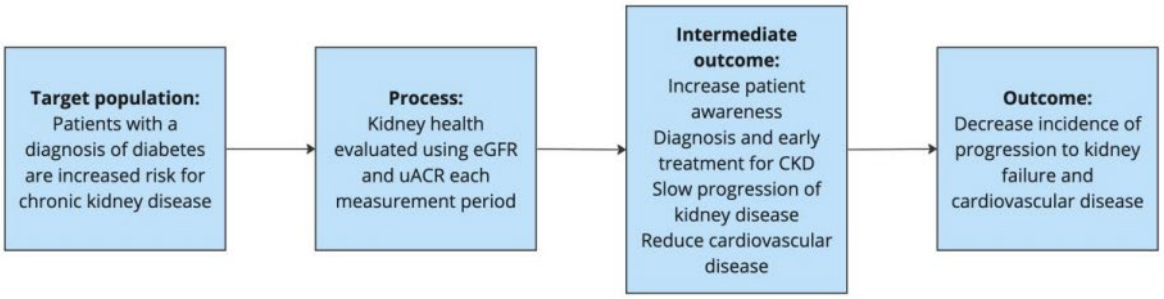

Figure 4. CBE #4315e Logic Model

Measure Evaluation Summary: CBE #4315e

Importance
Staff Preliminary Rating: Met
Importance: There is a business case for the measure along with supporting evidence for the importance of the measured process with demonstrated gap in performance.

Feasibility
Staff Preliminary Rating: Not met but addressable
Feasibility: The developer conducted a feasibility assessment across two ambulatory practices representing two electronic health record vendors, Allscripts and AthenaHealth. The developer identified some data elements that, while available in the electronic health record, were not in structured fields. The developer anticipates that these data elements will be feasible to collect in practices that provide home health care services, outpatient consultations, or care for hospice patients, as they are coded in a similar manner as Encounter, Performed: Annual Wellness Visit (a feasible data element). Additional feasibility testing to assess feasibility of these data elements in other sites should be considered by the developer.

Reliability	
Staff Preliminary Rating: Not met but addressable	
Testing Level:	Accountable Entity Level
Testing Method:	The developer conducted reliability testing using a **signal-to-noise** approach, and results reported show at least 75% of accountable entities are above 0.6 with a **median of 0.8**.
Reliability: Overall, the reliability testing shows at least 75% of accountable entities are above 0.6. At least six clinicians included in the analysis have only one patient each. These clinicians would each have reliability equal to 1.0 because they do not have multiple patients, so within-clinician variability is 0.0. The developer may consider expanding the testing to a larger sample for future evaluations.	

Validity	
Staff Preliminary Rating: Not met but addressable	
Testing Level:	Patient or Encounter Level
Testing Conducted:	Yes; the developer conducted validity testing using **inter-rater agreement testing with sensitivity and specificity analyses,** and results reported show agreement rates to be high for the denominator (94% overall agreement) and denominator exclusions (84% overall agreement).
Validity: The developer conducted data element validity testing in two ambulatory practices representing two electronic health record vendors, Allscripts and AthenaHealth. The developer found percent agreement rates to be high for the denominator (94% overall agreement) and denominator exclusions (84% overall agreement) and moderate for the numerator (50% overall agreement). Kappa values for two data	

Validity
elements critical to the calculation of the numerator (eGFR and uACR) were lower than 0.4 (indicating "poor" agreement). The developer explained that while the clinical sites that participated in testing are part of a system that provides ambulatory care and have more limitations in accessing laboratory data in discrete fields, in many health care systems (including ambulatory only) these elements are available for electronic reporting and agreement is expected to be higher. Additional testing to assess numerator validity in other sites should be considered by the developer.

Equity	
Staff Preliminary Rating: Met	
Equity considered:	Yes
Equity: The developer evaluated disparities in performance by subgroups (age, sex, race, ethnicity). The developer assessed how the measure contributes to efforts to address inequities in health care.	

Use & Usability	
Staff Preliminary Rating: Met	
Current or Planned Use:	Centers for Medicare & Medicaid Services (CMS) Merit-Based Incentive Payment System (MIPS)
Use & Usability: The measure is currently used on the MIPS program. The developer describes actions measured entities can take to improve performance.	

Public Comment[3]

Number of Comments Received: 4

Full text of developer/steward responses can be found on the PQM website.

Comment Summary	Support Level	Summary of Developer Response
One commenter expressed that this measure is important, and they were glad it is an eCQM and that the developer added the secondary eGFR.	Supportive	Thank you.
Two comments recommended the measure be modified:	N/A	1) The MIPS Kidney Health Evaluation measure was developed in parallel with the NCQA KED HEDIS measure. NKF will be

[3] Comments, as submitted, can be found on the PQM website.

Comment Summary	Support Level	Summary of Developer Response
1) By aligning with National Committee for Quality Assurance's (NCQA) Kidney Health Evaluation for Patients With Diabetes (KED) Healthcare Effectiveness Data and Information Set (HEDIS) measure. Using the same measure in MIPS and Medicare Advantage Star Ratings will reduce provider burden. The commenter also stated that the NCQA version more precisely measures kidney health evaluation. 2) While an imperfect approach, lowering the age limit to 75 years (e.g., screening individuals from 18-75) would reduce the likelihood of including persons with less than 5 years of life expectancy. If desired, this recommendation could be stratified by sex, with a cutoff of 70 years for men and 75 years for women. However, this may hinder implementation.		employing the same value sets employed by NCQA in our annual update to ensure alignment between these measures. 2) The age range in this measure is harmonized across the MIPS and HEDIS quality measure platforms. As this measure only requires testing, it allows for individualized interpretation of the results. Exclusions for hospice and palliative care services help to select seniors most likely to benefit from screening. Moreover, this is a patient safety issue in seniors, as medication safety is informed by eGFR (kidney function) to guide avoidance or dose adjustment of medications that are excreted and/or metabolized by the kidneys.
One comment questioned whether the measure produces scores that are sufficiently reliable as the minimum reliability was 0.42, which is below 0.7.	Non-Supportive	Our analyses show that approximately 80% of clinicians in the data set had reliability above 0.6. Lower reliability for some of the clinicians is likely due to a small number of patients attributed to the practice or larger variances in performance. We believe that the high rate of clinicians who achieved this reliability threshold is consistent with other measures that achieved endorsement. Regarding the agreement rates for the numerator, we note that the agreement between the electronic output from the electronic health record system is considered moderate and our analysis of the underlying causes on why the data might not be found in discrete fields is similar to what other developers encounter with measures that use laboratory results. Specifically, NKF continues to work to address these gaps such as the NKF Laboratory Engagement Initiative efforts to address how findings are reported when samples are insufficient to calculate. We believe that these issues are addressable and the ability to extract these data for the numerator will improve as use of the measure increases.

Advisory Group Feedback

Full text of developer/steward responses can be found on the PQM website.

Feedback/Questions	Summary of Developer Response
General Support: A committee member expressed strong support for the measure, noting that identifying kidney diseases earlier on has the potential to improve quality of life and save money, highlighting that we can currently make such a profound difference because of new medications, such as SGLT2 (sodium-glucose-cotransporter-2) inhibitors and Kerendia. They later added that, within their own health systems, they have seen chronic kidney disease (CKD) being caught more regularly because they have started using urine albumin-to-creatinine rations (uACRS).	The developer noted that kidney disease is underdiagnosed, that nine out of 10 people with kidney disease do not have a diagnosis, and only about 20% of patients who are at risk are tested. They said that we have many new classes of medications (such as SLGT2 inhibitor and mineralocorticoid receptor antagonist) and lifestyle modifications that can be implemented once kidney disease is identified. They also added that detection is necessary for awareness, and awareness is necessary for patient engagement and empowerment. They highlighted that this measure is also a Healthcare Effectiveness Data and Information Set (HEDIS) measure. A representative from the developer also shared that they included individuals with kidney disease on the technical expert panel (TEP), and those individuals expressed a strong desire for earlier detection, diagnosis, and patient engagement. The developer said they felt people living with kidney disease are very supportive of the measure. They also shared that they are working to expand this measure to hypertension, as rates of testing for hypertension are even lower than in diabetes. They are currently in the testing phase. *Summary Response Received after the Advisory Group meeting:* Chronic kidney disease (CKD) is underdiagnosed. Today nine out of 10 people with laboratory evidence of CKD do not have a diagnosis and only 20% of people at risk for CKD are tested annually in primary care settings. People living with CKD who receive both guideline-recommended tests (i.e., fulfill the proposed measure) are more likely to be referred to medical nutrition therapy and/or nephrology and receive evidence-based pharmaceutical interventions (ACEi, ARB, statins, SGLT2i) demonstrated to slow CKD progression and help reduce the associated cardiovascular risk. Blood pressure and A1c control is also more likely in individuals receiving both recommended

Feedback/Questions	Summary of Developer Response
	tests. The NKF is currently testing a version of this measure that evaluates CKD testing among people with hypertension.
Use/Usability: A committee member asked for clarification on which provider(s) are the intended user of the measure. They gave an example: If a patient has a nephrologist, a primary care physician (PCP), and an endocrinologist who are not in the same system, would that present a potential issue?	The measure is intended to improve screening for PCP screening/ testing for kidney disease and diagnosis/treatment because they do most of the care for patients with Type 2 diabetes. Because nephrologists and endocrinologists are involved later in the process, there are often not enough to take care of all diabetes patients, and because CKD is undertested for, the developer thought the risk of penalizing these providers was low. Any of these providers can satisfy the measure, but the PCP is the target. *Summary Response Received after the Advisory Group meeting:* The measure is intended to improve screening for PCP screening/ testing for kidney disease and diagnosis/treatment. PCPs have the greatest opportunity to improve early recognition and management of CKD, as PCPs do most of the care for patients with Type 2 diabetes and there are often not enough specialists to provide care to all diabetes patients. Raising awareness of this measure among endocrinologists can improve CKD testing among their patient populations, but the risk of penalizing these clinicians is low as they provide care for more advanced diseases. This measure provides limited risk for nephrologists, as referral to nephrology is premised upon a diagnosis of CKD associated with laboratory findings. Any of these providers can satisfy the measure, but the PCP is the target.
Feasibility in Capturing Hospice and Palliative Care: A committee member asked about the ability to capture data elements for hospice and palliative care in an ambulatory center.	The developer said they did not believe these populations would benefit from the measure because interventions may not be appropriate because of the care setting. They added that the feasibility challenges they experienced were not unique to their measure, and they believed the feasibility risk was acceptable. *Summary Response Received after the Advisory Group meeting:* Exclusions for hospice and palliative care services help to select people most likely to benefit from screening and diagnosis and intervention in CKD. The feasibility challenges that were experienced in capturing hospice and palliative care information in the EHR are not unique to our measure. We believe that the feasibility risk is acceptable, as this measure is associated with screening.

Feedback/Questions	Summary of Developer Response
Denominator Clarification: A committee member asked: Does the denominator include a visit in the measurement period (12 months) in any setting (e.g., inpatient, observation, emergency department)?	*Summary Response Received after the Advisory Group meeting:* The intent is an outpatient encounter because the measure is focused on PCPs. This may include either a face-to-face encounter or telehealth encounter.
Age Limit: A committee member asked: Why is the upper age 85 rather than not having an age limit?	The developer shared that deciding on an age limit was a hotly contested issue within their TEP. If one was to conceptualize this as a patient safety measure, then a no-age limit would be reasonable. The developer said that 85 was selected, in part, because there is less evidence for interventions in people over 85, potentially less benefits, and potentially more complications. They said the age could potentially be modified. *Summary Response Received after the Advisory Group meeting:* The upper limit for age was one of the more challenging aspects of measure development. The HEDIS internal review process changed the upper age limit from 18 to 75 years to 18 to 85 years–our goal is to harmonize the measure across MIPS and HEDIS quality measure platforms. We acknowledge that there are limited randomized controlled trial data evidence for CKD interventions that enroll patients aged 75 to 85 years, leaving uncertainty in the upper age limit for screening. However, screening is a patient safety issue in older persons because medication safety is informed by eGFR or kidney function to guide avoidance or dose adjustment of medications that are excreted and/or metabolized by the kidneys. As many as half of all FDA-approved drugs are metabolized or cleared by the kidneys.
Race Equity: A committee member mentioned that the Estimated Glomerular Filtration Rate (eGFR) had issues with health equity in terms of Black patients being measured differently than white patients.	The developer said that eGFR used to have a race coefficient. In 2021, new guidelines from National Kidney Foundation and the American Society of Nephrology recommended a new equation (CKD-EPI) that is race free. This is now being implemented in the United States, and most large, commercial, and academic labs have adopted the CKD-EPI equation, and it is an ongoing effort at smaller labs. The developer added the measure may help other labs adopt the new guidelines and take an incremental step toward health equity. *Summary Response Received after the Advisory Group meeting:*

Feedback/Questions	Summary of Developer Response
	The National Kidney Foundation and the American Society of Nephrology collaborated to recommend a new race-free approach to the estimation of glomerular filtration rate (eGFR). NKF employed an implementation strategy that resulted in all national laboratories employing this equation within 6 months of its publication. At present, approximately 65% of U.S. laboratories are now employing the race-free approach. NKF continues its efforts to ensure that all laboratories employ the 2021 CKD-EPI equation and is working with the laboratory community, CDC, and other agencies to advance its implementation.

Key Discussion Points:

- **Feasibility:** Kappa values for two data elements critical to the calculation of the numerator (eGFR and uACR) were lower than 0.4 (indicating "poor" agreement).
    - The developer explained that while the clinical sites that participated in testing are part of a system that provides ambulatory care and have more limitations in accessing laboratory data in discrete fields, in many health care systems (including ambulatory only) these elements are available for electronic reporting and agreement is expected to be higher. Does the committee have any concerns based on the developer's response?
- **Measure Alignment:** Does the committee have any concerns based on the alignment of this measure with other kidney health evaluation measures, such as the National Committee for Quality Assurance measure noted in the public comments?

CBE 3400: Use of Pharmacotherapy for Opioid Use Disorder [The Lewin Group/Centers for Medicare & Medicaid Services (CMS)]

Measure Description:

The Use of Pharmacotherapy for Opioid Use Disorder measure evaluates the percentage of Medicaid or Medicare-Medicaid participants, aged 18 years and older, who have been diagnosed with an opioid use disorder (OUD) who filled a prescription for, were administered, or dispensed, a Food and Drug Administration (FDA) -approved medication to treat or manage OUD during the measurement year.

Measure Status	
New or Maintenance: Maintenance Measure	**Used in An Accountability Application?** Yes - Quality Improvement with Benchmarking (external benchmarking to multiple organizations); Quality Improvement (Internal to the specific organization)
CBE Endorsement Status: Endorsed **Last Endorsement Review Cycle:** Spring 2018	**Proposed/Planned Use:** The CMS Medicaid Adult Core Set, Medicaid Innovation Accelerator Program (IAP), Center for Medicaid and CHIP Services (CMCS)

Measure Characteristics

Measure Type	Target Population(s)	Level of Analysis	Care Setting(s)
Process	Medicaid or Medicare-Medicaid beneficiaries aged 18 years and older	Population or Geographic Area	Behavioral Health: Inpatient, Outpatient; Emergency Department; Hospital: Acute Care Facility, Critical Access, Inpatient, Outpatient; Inpatient, Outpatient Rehabilitation Facility; Pharmacy

Measure Overview
Rationale: Pharmacotherapy for OUD is related to improved health outcomes, therefore, a quality measure to increase access to pharmacotherapy is expected to yield better care for beneficiaries with an OUD. Improved health outcomes associated with medications for OUD include reduced opioid use, overdose risk, and transmission of HIV and hepatitis C. While other measures evaluate pharmacotherapy administration rates, CBE #3400 includes an analysis at the state-level and requires prescription fills within the measurement year. In addition, there are typically fewer quality measures for Medicaid and high rates of OUD for this population.
Numerator: Medicaid beneficiaries with evidence of at least one prescription filled, or who were administered or dispensed an FDA-approved medication for OUD during the measurement year.
Denominator: Medicaid or Medicare-Medicaid beneficiaries aged 18 years and older with at least one encounter with a diagnosis of opioid abuse, dependence, or remission (primary or other diagnosis) at any time during the measurement year.
Exclusions: None. However, states may require exclusions, as appropriate, for their substance use disorder (SUD) programs and recipients.
Measure is Risk-Adjusted and/or Stratified: None

Logic Model
Summary: This logic model walks through the process of an individual who receives a diagnosis of OUD. This measure would analyze the second part of the logic model, where it tracks the number of individuals who begin medication to treat OUD. It then goes through the outcome of having individuals take the medication, with fewer adverse events occurring and the individual taking the medication going through remission.

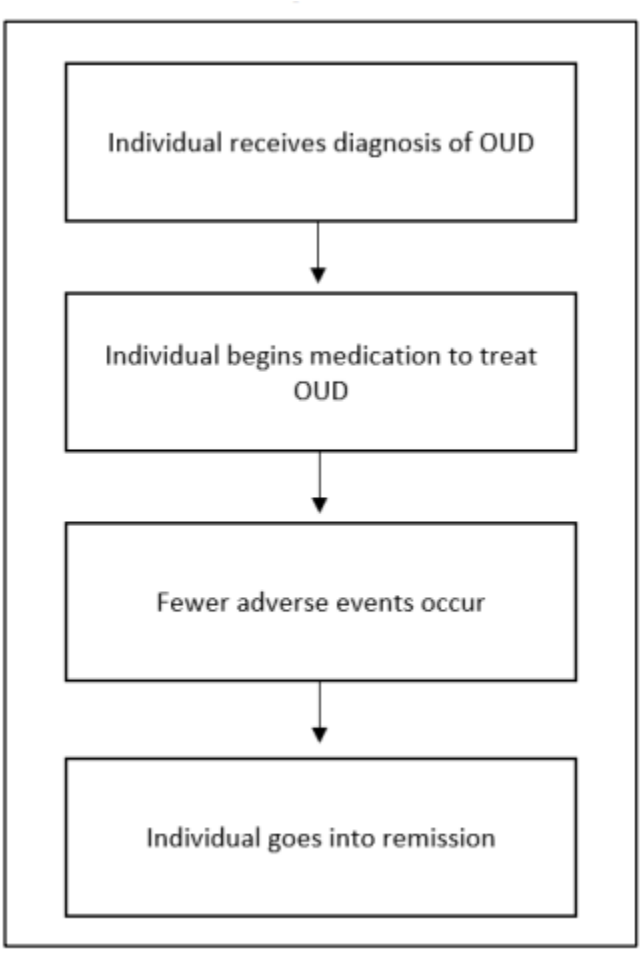

Figure 5. CBE #3400 Logic Model

Measure Evaluation Summary: CBE #3400

Importance
Staff Preliminary Rating: Met
Importance: The developer cites evidence to support the measure focus, including that a performance gap remains for this measure.

Feasibility
Staff Preliminary Rating: Met
Feasibility: Data are comprised of administrative claims or encounter data. Data collection does not involve sampling. The qualitative survey conducted indicated that there are minimal challenges for data collection and minimal burden to report. No changes were suggested nor made in response to multi-stakeholder panel feedback.

Reliability	
Staff Preliminary Rating: Met	
Testing Level:	Accountable Entity Level
Testing Method:	The developer conducted reliability testing using a **signal-to-noise analysis,** and results reported show an average state-level reliability of >0.6 for all reliability deciles for all five treatments across 50 states and the District of Columbia. The estimated reliability for the first decile for each treatment type is greater than 0.98.
Reliability: The measure is well-defined. Reliability is assessed at the state level. Reliability statistics are above 0.6.	

Validity	
Staff Preliminary Rating: Met	
Testing Level:	Accountable Entity Level
Testing Conducted:	Yes; the developer conducted validity testing using **face validity** and **convergent validity** testing. For the latter, correlations were assessed between CBE #3400 and the HEDIS® Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (IET) measure (measurement year 2021, 18 and older age stratification) and CBE #3453 Continuity of Care After Inpatient or Residential Treatment for Substance Use Disorder.
Validity: Face validity results indicated agreement by the technical expert panel to support the face validity of the measure. For empirical testing, the results show a strong correlation (0.7 or greater) between CBE #3400 and CBE#3453 and the HEDIS IET measures.	

Equity
Staff Preliminary Rating: Met

Equity	
Equity considered:	Yes
Equity: The developer described meaningful differences in measure rates for patients of different ages, races, sex, and dual eligibility status.	

Use & Usability	
Staff Preliminary Rating: Not met but addressable	
Current or Planned Use:	The CMS Medicaid Adult Core Set, Medicaid Innovation Accelerator Program (IAP), Center for Medicaid and CHIP Services (CMCS).
Use & Usability: The current use of the measure is documented; however, usability feedback was inconclusive and additional data are needed to understand potential barriers to use.	

Public Comment[4]

Number of Comments Received: 1

Full text of developer/steward responses can be found on the PQM website.

Comment Summary	Support Level	Summary of Developer Response
One comment asked if the developer had looked at Medicare Advantage, as older populations have a higher incidence of overdose. The commenter felt the measure was very important.	Supportive	Results from older adults enrolled dually in Medicaid and Medicare Advantage coverage are included in the results presented within the Full Measure Submission form. Thank you for the feedback.

Advisory Group Feedback

Full text of developer/steward responses can be found on the PQM website.

Feedback/Questions	Summary of Developer Response
Denominator: A committee member noted that there is a significant benefit to medication-assisted therapies for patients with opioid use disorder (OUD). However, a large population of those in remission for OUD decline to be on medication. The member wondered if this measure encourages or compels individuals in remission to be on medications and suggested that the individuals who are in remission	The developer said the primary focus is on individuals who have an active OUD diagnosis that occurs within the measurement period. They appreciated the suggestion and will take this comment back to be addressed internally. Stratification may be appropriate. *Summary Response Received after the Advisory Group meeting:*

[4] Comments, as submitted, can be found on the PQM website.

Feedback/Questions	Summary of Developer Response
for OUD and decline to be on medication be excluded from the denominator.	CBE #3400 focuses on evaluation of medication-assisted treatment (MAT) for beneficiaries diagnosed with an opioid use disorder. CMS acknowledges that treatments other than MAT may be appropriate for Medicaid beneficiaries; the care for these individuals would be evaluated by a different measure or quality-improvement initiative (e.g., a 12-Step Program; CBE #3312, CBE #3453 for continuity of care). This measure also fills a gap within medication-assisted treatment for opioid use disorder, especially at the state level. Thank you for your feedback.
Accountable Entity: A committee member asked for clarification about who would be held accountable under the measure.	The developer said the measure is a population-level measure, specifically at the state level. They added that there is variation in performance across the country, so if a state sees their performance results, they may be able to improve through their Medicaid program. *Summary Response Received after the Advisory Group meeting:* CBE #3400 evaluates quality of care at the state level. States can use the individual data points and performance scores for each medication-assisted treatment type to implement quality-improvement initiatives within their Medicaid programs and with managed care plans to improve quality over time. It is used in the Adult and Health Home Core Sets, including mandatory reporting by states beginning this year. Thank you for the feedback.
Care Settings: A committee member expressed concern about the broad array of care settings included in the measure.	The developer clarified that this is a state-level measure. The measure looks for the ICD-10 diagnosis code for OUD and does not specifically target a care setting. *Summary Response Received after the Advisory Group meeting:* CBE #3400 evaluates quality of care at the state level. States can use the individual data points and performance scores for each medication-assisted treatment type to implement quality-improvement initiatives within their Medicaid programs and with managed care plans to improve quality over time. Thank you for your feedback.

Feedback/Questions	Summary of Developer Response
OUD Diagnosis Code - Equity and Stigma: A committee member asked about the accuracy of the OUD diagnosis code, and if there may be equity issues attached to who is assigned a code that may have a stigma associated with it.	The developer said they must assume the documentation and claims are correct because payment is associated with them and states have various processes that audit claims for accuracy. The developer noted that most of the denominator population is white, and they are not seeing a disproportionate impact across racial groups but would have more specific data for the Recommendation Group. *Summary Response Received after the Advisory Group meeting:* Administrative claims data are assumed to be accurate as preciseness is critical to Medicare and Medicaid for timely and full payment for services. Medicare and Medicaid have processes to audit claims data to confirm their accuracy. Thank you for your feedback.
Defining Successful Treatment: A committee member commented that they felt this measure may communicate that the successful treatment of OUD is through a commercially sold pharmaceutical. They recommended including anyone in the numerator who has been to a substance use disorder provider and consider if the clinical decision may be appropriate.	The developer said the goal of the measure is to provide information rather than penalization (for example, in a pay-for-performance setting). The goal is not to reach 100% on the measure score because pharmacotherapy is not the appropriate treatment for everyone. The developer noted that the measure is claims based, and they are limited to what is available in the administrative claim. Potentially there may be information on behavioral therapy that is documented in a claim. They said they will convey this information to CMS. *Summary Response Received after the Advisory Group meeting:* CBE #3400 focuses on evaluation of medication-assisted treatment for beneficiaries diagnosed with an opioid use disorder. CMS acknowledges that treatments other than MAT may be appropriate for Medicaid beneficiaries; the care for these individuals would be evaluated by a different measure or quality-improvement initiative (e.g., a 12-Step Program; CBE #3312, CBE #3453 for continuity of care). This measure also fills a gap within medicated-assisted treatment for opioid use disorder, especially at the state level. Thank you for your feedback.

Feedback/Questions	Summary of Developer Response
Target Population: A committee member asked why is Medicaid being used as the target population rather than anyone who has an OUD?	The developer said the measure focuses primarily on Medicaid because of their contract's scope; the 2018 version of this measure was limited to Medicaid patients 18-64 years old, and this measure expands the population to include 18 years and older who are dually enrolled in Medicare and Medicaid. The developer noted they do not have access to commercial claims data or alternative payments. They added that they have sometimes seen commercial plans pick up their measures. *Summary Response Received after the Advisory Group meeting:* CMS and the Lewin Group do not have access to administrative data from payers other than Medicare and Medicaid (e.g., commercial or non-profit data). The technical specifications for CBE #3400 are available to anyone who wishes to implement this measure within their claims environment. Thank you for the feedback.

Key Discussion Points:

- **Usability:** The developer reported that no substantive comments have been received on this measure from the public or accountable entities. Does the committee have any insight on potential barriers encountered from the use of this measure?
- **Unintended Consequence:** A few committee members expressed concern over encouraging the use of pharmacotherapy to the detriment of the patient themselves or other therapies that may already be working or be more appropriate for a certain patient.
    - The developer noted that the goal of this measure is to provide information rather than penalization, and that the goal is not to reach 100%, as pharmacotherapy may not be appropriate for everyone. The developer further noted that it will continue to explore this topic with CMS.