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National Consensus Development and Strategic Planning for Health Care Quality Measurement

Final Fall 2023 Cycle Endorsement and Maintenance (E&M) Technical Report

PRIMARY PREVENTION

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Table of Contents

List of Tables

List of Figures

Executive Summary

Over the past 20+ years, the United States (U.S.) has been focused on improving health care quality for Americans. Health care quality measures have increasingly been developed and used to facilitate this goal by quantifying the quality of care provided by health care providers and organizations based on various standards of care. These standards relate to the effectiveness, safety, efficiency, person-centeredness, equity, and timeliness of care.[1]

At Battelle, we have a strong collective interest in ensuring that the health care system works as well as it can. Quality measures are used to support health care improvement; benchmarking; accountability of health care services; and to identify weaknesses, opportunities, and disparities in care delivery and outcomes.[1,2]

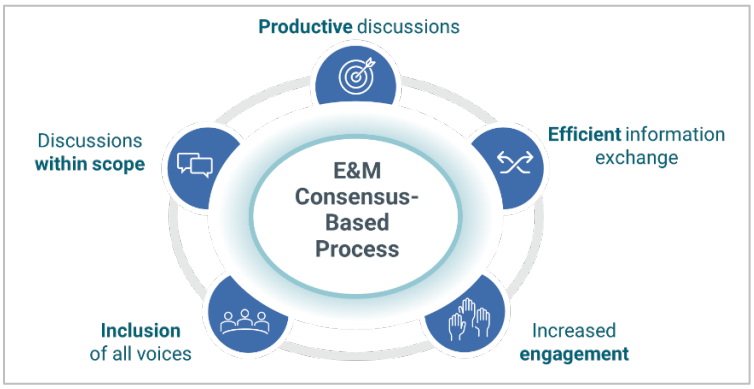

Figure ES-1. E&M Consensus-Based Process

Battelle is a certified 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. As a CMS-certified CBE, we facilitate the review of quality measures for endorsement. To support our consensus-based process, we formed the Partnership for Quality Measurement™ (PQM), which ensures informed and thoughtful endorsement reviews of quality measures across a range of focus areas that align with a person's journey through the health care system.

One of those focus areas is Primary Prevention, which includes measures that focus on preventing disease or injury before it occurs by altering unhealthy or unsafe behaviors and increasing resistance to disease, should exposure occur. A major area of preventative health care in the U.S. today has been reduction of exposure to the unnecessary and unsafe use of opioids. From 1999 to 2021, the toll of opioid-related overdoses, involving both prescription and illicit opioids, amounted to approximately 645,000 lives lost.[3] The safe use of opioids is a critical aspect of primary prevention within the realm of health-related lifestyle behaviors and the prevention of substance abuse.[4]

Concurrent prescribing of opioids, in which patients receive multiple opioid prescriptions simultaneously or in combination with other psychoactive drugs, such as benzodiazepines, increases the risk of overdose and other adverse outcomes.[5] To address this concern, the 2022 Center for Disease Control and Prevention (CDC) Clinical Practice Guideline for Prescribing Opioids for Pain outlines recommendations to assist clinicians in enhancing communications with patients about the benefits and risks of pain treatments. The guideline is also intended to enhance the safety and effectiveness of pain treatment, alleviate pain, improve the function and

quality of life for patients experiencing pain, and concurrently reduce the associated risks of opioid pain therapy. [6]

For this measure review cycle, three measures were submitted to the Primary Prevention committee for endorsement consideration. Two measures, one new and one up for maintenance endorsement review, were withdrawn by the measure steward prior to the committee review (Table 4), which resulted in the new measure not receiving an endorsement decision and in removal of endorsement for the maintenance measure. The remaining measure reviewed by the Primary Prevention committee (Figure ES-2) received an endorsed with conditions decision (Table ES-1).

Table ES-1. Measures Reviewed by the Primary Prevention Committee

CBE Number	Measure Title	New/Maintenance	Developer/Steward	Final Endorsement Decision
3316e	Safe Use of Opioids-Concurrent Prescribing	Maintenance	Mathematica/Centers for Medicare & Medicaid Services	Endorsed with Conditions

Figure ES-2. Fall 2023 Measures for Committee Review

Endorsement and Maintenance (E&M) Overview

Battelle's E&M process ensures measures submitted for endorsement are evidence-based, scientifically sound, and both safe and effective, meaning use of the measure will increase the likelihood of desired health outcomes; will not increase the likelihood of unintended, adverse health outcomes; and is consistent with current professional knowledge.

Each E&M cycle (e.g., Fall or Spring) has a designated Intent to Submit deadline, during which measure developers/stewards must submit key information (e.g., measure title, type, description, specifications) about the measure. One month after the Intent to Submit deadline (Table 1), measure developers/stewards submit the full measure information by the respective Full Measure Submission deadline.

The measures are then posted to the PQM website for a 30-day public comment period, which occurs prior to the endorsement meeting. The intent of this 30-day comment period is to solicit both supportive and non-supportive comments with respect to the measures under endorsement review. Any interested party may submit a comment on any of the measures up for endorsement review for a given cycle (e.g., Fall or Spring). All public comments received during this 30-day period are posted to the respective measure page on the PQM website for full transparency. Summaries of the comments received for the measure submitted to the Primary Prevention Committee are provided below. The committee considered all comments in its endorsement evaluation of the measure.

Table 1. Intent to Submit and Full Measure Submission Deadlines by Cycle

E&M Cycle	Intent to Submit*	Full Measure Submission*
Fall	October 1	November 1
Spring	April 1	May 1

**Deadlines are set at 11:59 p.m. (ET) of the day indicated. If the deadline ends on a weekend or holiday, the deadline will be the next immediate business day.*

E&M committees are composed of diverse PQM members, representing all facets of the health care system. There are five E&M projects, each having a committee that evaluates, discusses, and assigns endorsement decisions for measures under endorsement review. Each E&M project committee is divided into an Advisory Group and a Recommendations Group (Figure 1).

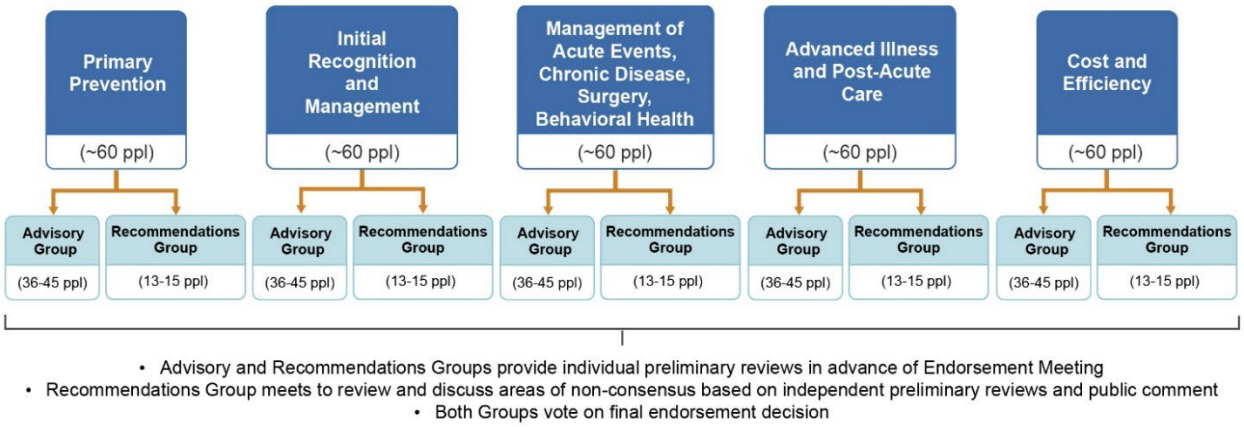

Figure 1. E&M Committee Structure

The goal is to create inclusive committees that balance experience, expertise, and perspectives. The E&M process convenes and engages interested parties throughout the cycle. The interested parties include those who are impacted or affected by quality and cost/resource use who come from a variety of places and represent a diverse group of people and perspectives (Figure 2 and Figure 3).

Figure 2. E&M Interested Parties

With respect to the Primary Prevention committee, membership consisted of 10 patient partners (i.e., patients, caregivers, advocates) and 18 clinicians, with specialties in nursing, preventive medicine, nephrology, patient safety, population health, and others (Figure 3). The committee also included five experts in rural health and six in health equity.

All committee members completed a measure-specific disclosure of interest (MS-DOI) form to identify potential conflicts with the measures under endorsement review for the respective E&M cycle. Members were recused from voting on measures potentially affected by a perceived conflict of interest (COI) based on Battelle's COI policy. While a list of committee members is provided in Appendix A, full committee rosters and bios are posted on the respective project pages on the PQM website.

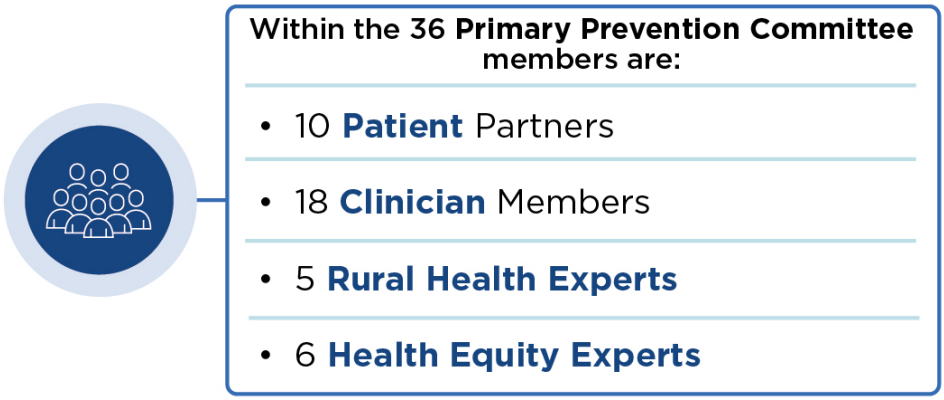

Figure 3. Primary Prevention Committee Members

During the endorsement meeting, Advisory Group members listen to the Recommendations Group discussions before both groups cast an endorsement vote (Figure 4). This structure ensures a larger number of voices contribute to the consensus-building process.

Advisory Group	Recommendations Group
• Reviews and provides ratings and written comments on measures prior to the endorsement meeting. • Attends the endorsement meeting to **listen** to the Recommendations Group discussions. • Votes on measure endorsement decisions during the meeting.	• Reviews and provides ratings and written comments on measures prior to the endorsement meeting. • Attends the endorsement meeting to **discuss** areas of disagreement (i.e., lack of consensus) identified from the preliminary measure ratings from both groups. • Votes on measure endorsement decisions during the meeting.

Figure 4. E&M Advisory Group vs. Recommendations Group

At least three weeks prior to an E&M committee endorsement meeting, the Recommendations Group and the Advisory Group receive the full measure submission details for each measure up for review, including all attachments, the PQM Measure Evaluation Rubric, the public comments received for the measures under review, and the E&M team preliminary assessments.

Members of both groups were asked to review each measure, independently, against the PQM Measure Evaluation Rubric. Committee members assigned a rating of "Met," "Not Met but Addressable," or "Not Met" for each domain of the PQM Measure Evaluation Rubric. In addition, committee members provided associated rationales for each domain rating, which were based on the rating criteria listed for each domain. Battelle staff aggregated and summarized the results and distributed them back to the committee, and to the respective measure developers, and/or stewards, for review within one week of the endorsement meeting. These independent committee member ratings were compiled and used by Battelle facilitators and committee co-chairs to guide committee discussions.

Under the Battelle process, measures reach their endpoint when an endorsement decision is rendered by the E&M project committees (Table 2).

Table 2. Endorsement Decision Outcomes

Decision Outcome	Description	Maintenance Expectations
Endorsed	**Applies to new and maintenance measures.** There is 75% or greater agreement for endorsement via a vote by the E&M committee.	Measures undergo maintenance of endorsement reviews every 5 years with a status report submission at 3 years (*see Status Report/Annual Update for more details*).±
Endorsed with Conditions*	**Applies to new and maintenance measures**. There is 75% or greater agreement via a vote by the E&M committee that the measure can be endorsed, as it meets the criteria, but there are recommendations/areas committee reviewers would like to see when the measure comes back for maintenance. If these recommendations are not addressed, then a rationale from the developer/steward should be provided for consideration by the E&M committee review.	Measures undergo maintenance of endorsement reviews every 5 years with a status report submission at 3 years (*see Status Report/Annual Update for more details*), unless the E&M committee assigns a condition requiring the measure to be reviewed earlier.

Decision Outcome	Description	Maintenance Expectations
		At maintenance review, the E&M committee evaluates whether conditions have been met, in addition to all other maintenance endorsement minimum requirements.
Not Endorsed°	**Applies to new measures only**. There is 75% or greater agreement via a vote by the E&M committee to not endorse the measure.	None
Endorsement Removed°	**Applies to maintenance measures only.** Either: • There is 75% or greater agreement for endorsement removal by the E&M committee; or • A measure steward retires a measure (i.e., no longer pursues endorsement); or • A measure steward never submits a measure for maintenance and there is no response from the steward after targeted outreach; or • There is no longer a meaningful gap in care, or the measure has plateaued (i.e., no significant change in measure results for accountable entities over time).	None

±Maintenance measures may be up for endorsement review earlier if an emergency/off-cycle review is needed.

**Conditions are determined by the E&M committee, with the consideration of what is feasible and appropriate for the developer/steward to execute by the time of maintenance endorsement review.*

°Measures that fail to reach the 75% consensus threshold are not endorsed.

The "Endorsed with Conditions" category serves as a means of endorsing a measure, but with conditions set by the committee. These conditions take into consideration what is feasible and appropriate for the developer/steward to execute by the time of maintenance endorsement review.

After the E&M endorsement meeting, E&M committee endorsement decisions and associated rationales are posted to the PQM website for three weeks, which represents an appeals period, during which any interested party may request an appeal regarding any E&M committee endorsement decision. If a measure's endorsement is being appealed, including an "Endorsed with Conditions" decision, the appeal must:

- Cite evidence of the appellant's interests that are directly and materially affected by the measure, and the CBE's endorsement of the measure has had, or will have, an adverse effect on those interests; and
- Cite the existence of a CBE procedural error or information that was available by the cycle's Intent to Submit deadline but was not considered by the E&M committee at the time of the endorsement decision, which is reasonably likely to affect the outcome of the original endorsement decision.

In the case of a measure not being endorsed, the appeal must be based on one of two rationales:

- The CBE's measure evaluation criteria were not applied appropriately. For this rationale, the appellant must specify the evaluation criteria they believe was misapplied.
- The CBE's E&M process was not followed. The appellant must specify the process step, how it was not followed properly, and how this resulted in the measure not being endorsed.

If an eligible appeal is received, we convened the Appeals Committee, consisting of the co-chairs from all five E&M project committees, to review and discuss the appeal. The Appeals Committee concludes its review of an appeal by voting to uphold (i.e., overturn a committee endorsement decision) or deny (i.e., maintain the endorsement decision) the appeal. Consensus is determined to be 75% or greater agreement via a vote among members.

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For the Fall 2023 cycle, the appeals period opened on February 26 and closed on March 18, 2024. No appeals were received for the measures reviewed by the Primary Prevention committee.

Primary Prevention Measure Evaluation

For this measure review cycle, the Primary Prevention committee evaluated one measure undergoing maintenance review against standard measure evaluation criteria. During the endorsement meeting, the committee voted to endorse the measure with conditions (Table 3).

Brief summaries of the committee's deliberations for the measure along with the conditions for endorsement are noted under the measure's evaluation summary below. The committee's endorsement meeting summary can be found on the respective E&M project page on the PQM website.

Table 3. Number of Fall 2023 Primary Prevention Measures Submitted and Reviewed

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

**Measure developers/stewards can withdraw a measure from measure endorsement review at any point before the committee endorsement meeting. Table 4 provides a summary of withdrawn measures.*

Table 4. Measures Withdrawn from Consideration

Measure Number	Measure Title	Developer/Steward	New/Maintenance	Reason for Withdrawal*
3136	GAPPS: Rate of preventable adverse events per 1,000 patient-days among pediatric inpatients	Center of Excellence for Pediatric Quality Measurement	Maintenance	Steward no longer seeks to maintain endorsement

Measure Number	Measure Title	Developer/Steward	New/Maintenance	Reason for Withdrawal*
4215e	CVD Risk Assessment Measure- Proportion of pregnant/postpartum patients who receive CVD Risk Assessment with a standardized tool	University of California, Irvine/Centers for Medicare & Medicaid Services	New	Withdrawn and deferred to future cycle

**Endorsement was removed for maintenance measures that were retired by the measure steward.*

Public Comments Received Prior to Committee Evaluation

Battelle accepts comments on measures under endorsement review through the PQM website. For this evaluation cycle, the pre-evaluation commenting period opened on December 1, 2023, and closed on January 2, 2024. Three pre-evaluation comments were submitted and shared with the committee prior to the measure evaluation meeting on February 7, 2024. A summary of the comments received is provided under the measure's evaluation summary below.

Summary of Potential High-Priority Gaps

During the committee's evaluation of the measure, no potential high-priority measurement gap areas emerged.

Summary of Major Concerns or Methodological Issues

The following brief summary highlights a major concern that the committee considered.

Unintended Consequences Associated with Abrupt Medication Discontinuation

During its review of CBE #3316e, the committee raised concern with the potential unintended consequence of abruptly discontinuing opioids and/or benzodiazepines. For people who become physically dependent on these medications, the committee underscored that abrupt or inappropriately rapid discontinuation of opioids or benzodiazepines can lead to serious withdrawal symptoms, uncontrolled pain, and suicide.

Since CBE #3316e is focused on evaluating and potentially discontinuing these medications at discharge, the committee urged the developer to evaluate, through stratification if possible, new and current users of opioids and benzodiazepines upon admission.

Measure Evaluation Summaries

CBE # 3316e – Safe Use of Opioids – Concurrent Prescribing [Mathematica/Centers for Medicare & Medicaid Services] – *Maintenance*

Specifications | Committee Independent Review Summary

Description: Proportion of inpatient hospitalizations for patients 18 years of age and older prescribed, or continued on, two or more opioids or an opioid and benzodiazepine concurrently at discharge.

Committee Final Vote: Endorsed with Conditions

Conditions:

- Expand reliability and validity testing beyond the sample used in current submission to ensure a more diverse population and explore regional diversity within testing.
- Explore new versus current users of opioids and benzodiazepines on admission, and if feasible, stratify the data by these populations.

Vote Count: Endorse (2 votes; 7.14%), Endorse with Conditions (24 votes; 85.71%), Remove Endorsement (2 votes; 7.14%); recusals (1).

Summary of Public Comments: Prior to the endorsement meeting, Battelle received three public comments. One comment, which supported the measure, highlighted the significance of prescription management in safeguarding patients from the adverse effects of long-term opioid use. Another comment noted the increased risk to providers due to the measure's inadequate robustness. The last comment suggested that the patient population receiving post-acute rehabilitation services should be incorporated into the measure's exclusion list.

Appeals: None.

Discussion Theme	Recommendations Group Discussion
Reliability and Validity	• The committee expressed concerns about the homogeneity of the patient population in the testing sample. In response, the developer noted they were limited to data from hospitals recruited to participate in the testing. • While the committee expressed concerns about the lack of information on hospital types in testing, the developer noted their plan to expand testing based on rural-urban area codes. • The committee also raised concern with the small sample size, consisting of 11 urban teaching hospitals, 10 of which belong to the same health system, spanning two states. The developer, in response, cautioned against artificially increasing the sample size, emphasizing the strength of the existing sample size in revealing important information.

Discussion Theme	Recommendations Group Discussion
Patient Perspective	• Committee members acknowledged the measure's significance to patient safety but raised concerns about the absence of the patient perspective in the measure's development. • The committee emphasized the importance of educating patients about changes in their care and gaining input on how patients and family members find this measure to be meaningful, particularly as it relates to patients relying on opioids for pain management and facing the prospect of having their medication discontinued after their hospital stay.
Equity Considerations	• The committee discussed stratification by elements such as language spoken, area deprivation index, socioeconomic status, gender, ethnicity, and race to address equity-based concerns. • The committee also underscored the complexity of self-identification of some of the patient characteristics, and suggested the developer take this into consideration. • The committee highlighted the importance of understanding how this measure can identify the rural-urban divide with respect to the measure focus. • Acknowledgements from the developer indicated potential exploration of these equity considerations in the future.
Potential for Unintended Consequence	• Committee members sought to understand the potential for abruptly discontinuing a patient's opioid and benzodiazepine prescription, by encouraging the developer present data on new vs. current users of these medications upon admission. • The developer noted that this may not be feasible and stratifying the measure in this way would change the measure specifications. • Committee members remained cautious, placing a condition on the measure for the developer to explore new versus current users of opioids and benzodiazepines on admission, and if feasible, stratify the data by these populations.

Additional Recommendations for the Developer/Steward and Future Directions

The committee encouraged the developer to explore the use of patient education videos to empower patients to understand changes to their care process and making those easily accessible via a smartphone application.

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Appendix A: Primary Prevention Committee Roster

Fall 2023 Cycle

Member	Affiliation/Organization	Advisory or Recommendation Group
Quinyatta Mumford *(Patient Representative Co-chair)*	Mumford and Associates	Recommendation
John Krueger *(Non-Patient Representative Co-chair)*	The Chickasaw Nation Department of Health	Recommendation
Adelisa Perez-Hudgins	New Jersey Health Care Quality Institute	Recommendation
Amir Qaseem	American College of Physicians	Advisory
Christa Starkey	S.W. Zimostrad and Associates P.C.	Recommendation
Daniel Kelley	Wellframe	Recommendation
David Pryor	Intermountain Health	Advisory
Heather Napier	Baptist Health Corbin	Advisory
Jean Morris	Maricopa Integrated Health System	Advisory
Jeff Brady	Enterprise Research & Innovation, Highmark Health	Advisory
Jenna Williams-Bader	National Quality Forum	Recommendation
Jennifer Rozenich	Cook County Health System	Advisory
Jessica Hill	-	Recommendation
Joanne Campione	Westat	Recommendation
Jon Burdick	St Joseph Hospital	Advisory
Kevin Bowman	Elevance	Recommendation
Kimberly Rodgers	-	Advisory
Lawrence (Larry) Kraft	Edgar May Health and Recreation Center	Advisory
Lucy Marius	Federal Highway Administration	Advisory
Mahir Hussein	-	Advisory
Melissa Eggen	University of Louisville School of Public Health and Information Sciences	Advisory
Michael Ho	VA Eastern Colorado Health Care System and University of Colorado School of Medicine and American Heart Association	Advisory

Member	Affiliation/Organization	Advisory or Recommendation Group
Padmaja Patel	American College of Lifestyle Medicine; World Lifestyle Medicine Organization; Wellvana	Advisory
Pamela L. Sartin	Chota Community Health Services	Recommendation
Paula Farrell	Lantana Consulting Group	Advisory
Peter Herrera	-	Advisory
Pooja Kothari	X4 Health	Advisory
Ramsey Abdallah	Northwell Health	Advisory
Rebekah Angove	Patient Advocate Foundation	Advisory
Robert R. Mayo	Rochester Regional Health	Recommendation
Sandeep Vijan	University of Michigan Health	Advisory
Shoshana Levy	CVS/Aetna	Advisory
Terra Stump	Quality Insights; Mathematica	Recommendation
Tim Laios	Health Services Advisory Group, Inc.	Recommendation
Timothy Switaj	West Region, WellSpan Health	Advisory
Zhenqiu Li	Yale Center for Outcomes Research and Evaluation	Advisory

Partnership for Quality Measurement Organizations

Battelle

Institute for Healthcare Improvement

Rainmakers

Measure Stewards

Centers for Medicare & Medicaid Services (CMS)

Measure Developers

Mathematica


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