Endorsement and Maintenance (E&M) Guidebook

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July 12, 2024

Meet the E&M Leadership Team

Nicole Brennan | Executive Director

- Provides strategic and operational oversight
- 20+ years' health care, public health, and quality experience

Brenna Rabel | Deputy Director

- Facilitates collaboration across CBE activities to ensure consistency and excellence
- 10+ years' health care, public health, and quality experience

Jeffrey Geppert | Sr. Research Leader

- Leads Measurement Science team for E&M
- 25+ years' measurement science, health care, and quality experience

Matthew Pickering | E&M Task Lead

- Oversees E&M processes and activities
- 10+ years' quality experience

Anna Michie | E&M Deputy Task Lead

- Provides strategic and technical support on E&M processes and activities
- 10+ years' quality experience

CBE: consensus-based entity

Agenda

- Enhancements to the Endorsement and Maintenance (E&M) Guidebook and Review of Public Comments
  - Committee Composition, Roles, and Responsibilities
  - Public Comment
  - Requirements for Measure Consideration
  - PQM Measure Evaluation Rubric
  - Conditions for "Endorsed with Conditions" Designation
  - Appeals Eligibility Criteria
  - Clarifications to Endorsement Maintenance

- Review PQM Engagement Opportunities

- Questions and Open Discussion

Enhancements to the E&M Guidebook, Processes, and Policies

1. Changes in committee size, name, convening, and voting

2. Updates to measure public commenting opportunities

3. Added requirements for measures to be considered for endorsement

4. Changes to the PQM Measure Evaluation Rubric

5. Updates to the conditions for the "Endorsed with Conditions" designation

6. More detail and clarity on appeals criteria and what the appeal must include

7. More clarity on maintenance endorsement, including adding a status report and updated policy for deferrals

Comments Overview

- Public comment period was from June 4–24.
- Battelle received **comments from five organizations and one individual**.
  - American Medical Association
  - Center for Healthcare Quality and Payment Reform
  - Health Services Advisory Group
  - American College of Physicians
  - Memorial Hermann Health System
- Comments focused on various aspects of the guidebook (Table 1).

Table 1. Number of Comments by Category

Comment Category	Number of Comments
General	4
Committee Structure & Voting	3
Public Comment Opportunities	1
E&M Policies	5
PQM Measure Evaluation Rubric	9
Endorsed with Conditions Designation	2
Appeals and Maintenance Requirements	1

Enhancements to the Endorsement and Maintenance (E&M) Guidebook

Number of Comments

4

Summary

1. The E&M Guidebook is well put together and is an excellent tool for endorsement.

2. Comments about transparency, engagement, and time for input with respect to E&M process revisions.

Public Comments

Number of Comments

4

Summary

3. Consider changing the title of E&M Guidebook to "Measure Endorsement & Management," as E&M is well-known for Evaluation & Management Current Procedural Terminology Codes (E&M Codes).

4. Battelle should reconsider when E&M process changes will take effect, as developers need time to address any new requirements.

Advisory (Delphi) Group

- **Reviews measures and provides feedback and questions** regarding the measures under review during Advisory Group meetings 1-2 months prior to the Recommendation Group endorsement meeting.

- These inputs ensure a larger number of voices contribute to the consensus-building process.

Recommendation (Nominal) Group

- **Reviews and provides ratings and written comments on measures** prior to the Recommendation Group endorsement meeting.

- **Reviews the Advisory Group's feedback and questions, public comments, and respective developer/steward responses** pertaining to the measures under review prior to the endorsement meeting.

- **Renders an endorsement decision via a vote** during the endorsement meeting.

- As needed, the membership of the Recommendation Group may be augmented with individuals with specialized expertise recruited from other E&M committees.

- Developers/stewards are encouraged to invite their own subject matter experts.

Roster Category	2024 Advisory Group Targets	2024 Recommendation Group Targets
Patients, families, caregivers, patient advocates	8	4
Clinicians, including physicians, nurses, pharmacists, physical therapists, etc.	3	5
Facilities and institutions, including accountable care organizations (ACOs), hospitals/hospital systems, and post-acute/long-term care facilities	3	5
Purchasers and plans (state, federal, and/or private)	5	3
Rural health experts	2	2
Health equity experts	2	2
Researchers in health services, alternative payment models, and population health	6	2
Other interested parties (representatives of electronic health record [EHR] vendors, provider and facility associations, and experts in areas such as quality improvement/ implementation science, care coordination, patient safety, behavioral health, and national policymakers)	6	2
Total	**35***	**25***

Totals may fluctuate between 35-40 for the Advisory Group and 20-25 for the Recommendation Group.

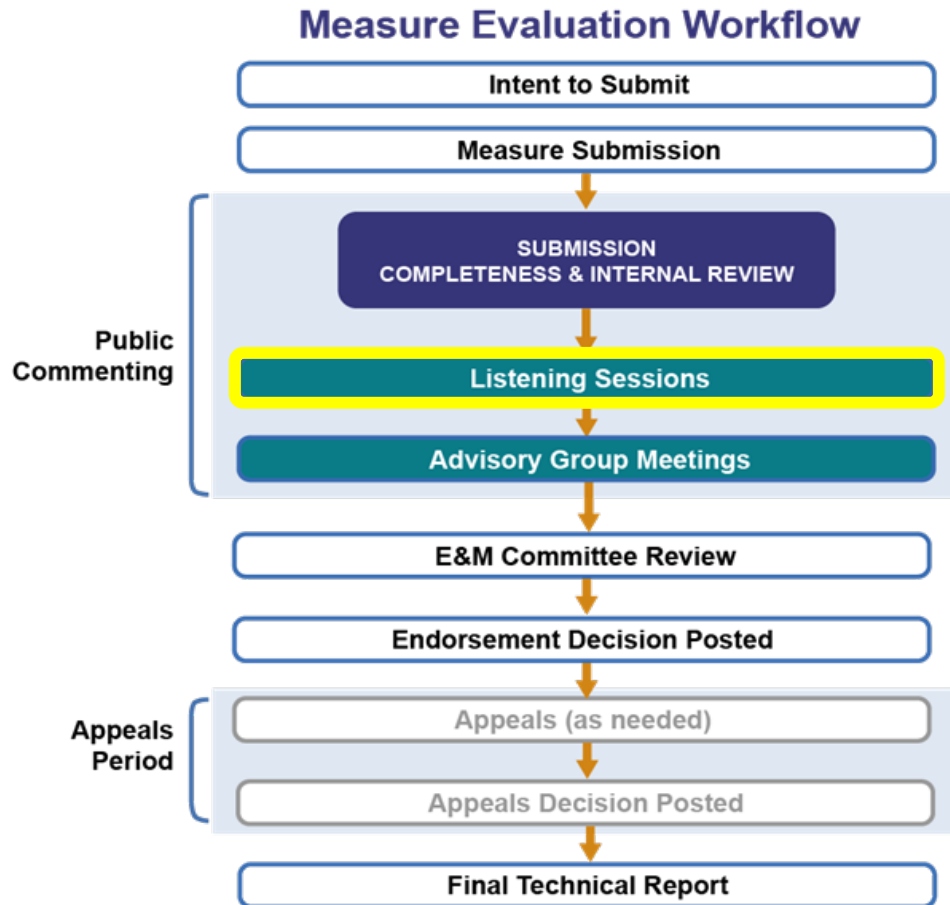**Number of Comments**

3

Summary

1. Need for more visibility on E&M committee members serving on either Advisory or Recommendation Groups.

2. Full committee should vote on the measures (not just Recommendation Group) to ensure full range of perspectives are considered.

3. Battelle should survey committee members for meeting availability to help achieve quorum.

2. Updates to Public Comment Opportunities *(Spring 2024)*

Measure Evaluation Workflow

Intent to Submit

Measure Submission

Public Commenting

SUBMISSION COMPLETENESS & INTERNAL REVIEW

Listening Sessions

Advisory Group Meetings

E&M Committee Review

Endorsement Decision Posted

Appeals Period

Appeals (as needed)

Appeals Decision Posted

Final Technical Report

- 30-day public commenting period occurs prior to the endorsement meeting and concurrently with E&M staff assessments.

- Prior to the end of the public commenting period, Public Comment Listening Sessions are held.

- Listening session transcripts are shared publicly and with developers/stewards for review and response.

- Developer responses to public comments are shared with committee prior to endorsement meetings.

**Number of Comments**

1

Summary

1. Battelle should reconsider the current timeline, as public comment occurs at the same time as much of the work for Pre-Rulemaking Measure Review (PRMR) and Measure Set Removal (MSR).

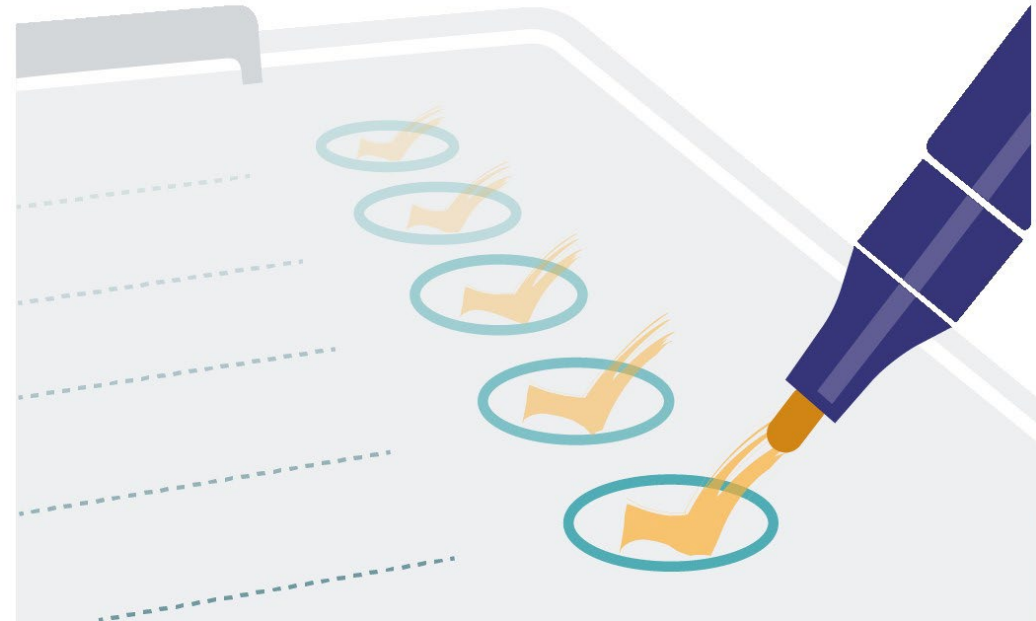# 4. E&M Policies:
Requirements for Measure Consideration

❑ The developer **signs a Quality Measure Developer and Steward Agreement (QMDSA)** form.*

❑ The measure **must include data from the past 5 years**.

❑ The developer **fully specifies the measures and tests** for reliability and validity.

❑ The **measure specifies a responsible entity** (i.e., accountable entity) and any analyses conducted are performed using the data source(s) and level(s) of analysis for which the measure is specified.

❑ The **intended use of the measure includes accountability applications** to achieve high-quality efficient health care.

❑ **The measure submission information is complete**.

If the steward is a governmental organization, a QMDSA is not required.
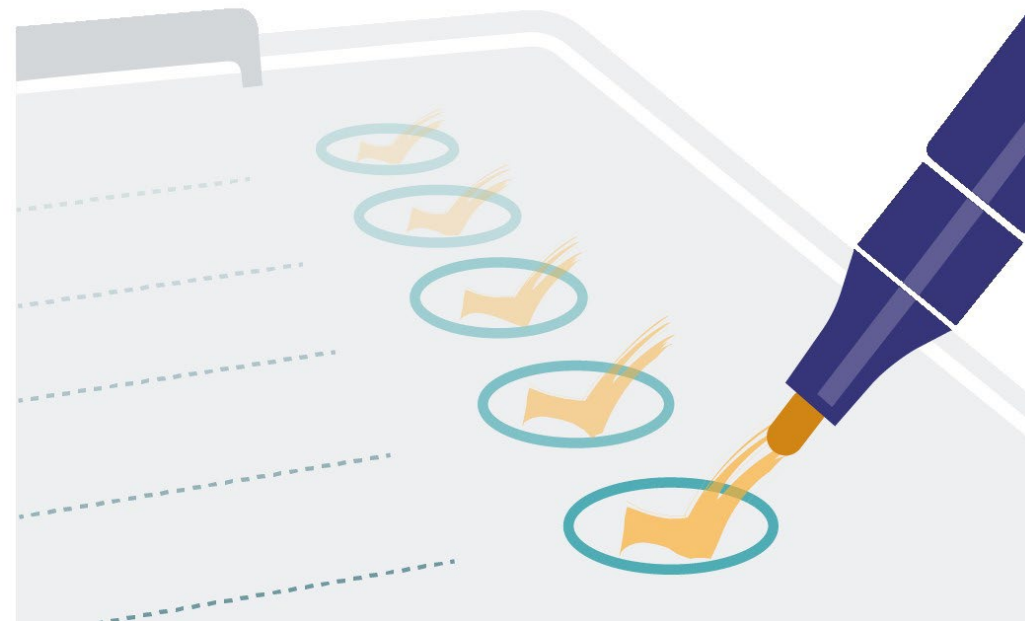
4. E&M Policies:
CBE Policy on Instrument-based Clinical Quality Measures

- The CBE **does not review or endorse instruments or surveys**.

- The developer **must specify, and test** clinical quality measures derived from instruments or surveys **at the accountable entity-level** (e.g., clinician or facility).

- There are **no differences in the requirements or criteria for endorsement & maintenance** between instrument-based clinical quality measures and other clinical quality measures.

- The CBE **reviews and endorses each clinical quality measure** derived from an instrument or survey, **separately**.

- Developers/stewards are encouraged, where appropriate, to **combine individual instrument or survey items into a person/respondent-level [composite](),** which may then be aggregated to the accountable entity-level. Such a measure would be reviewed and endorsed as a single measure.

Number of Comments

5

Summary

1. Endorsement should state the appropriateness of use (e.g., public reporting, payment, quality improvement).

2. Battelle should require annual updates of endorsed measures.

5. PQM Measure Evaluation Rubric

Summary of Rubric Enhancements:

- More specificity on whether requirements apply to measures seeking initial endorsement or those under maintenance review.

- Added requirements for Scientific Acceptability (i.e., reliability and validity).

5. PQM Measure Evaluation Rubric
Importance

Enhancements:

- **For initial endorsement:**
  - There must be a description of other existing measures or programs, OR
  - Evidence that a search was conducted to identify other existing measures or programs.

- **For maintenance:**
  - There must be at least moderate certainty that there is evidence of a performance gap.

Enhancement:

- Equity will remain an optional criterion for the Fall 2024 cycle. However, this domain has moved to come after Importance.

5. PQM Measure Evaluation Rubric
Feasibility

Enhancements:

- **For initial endorsement:**
  - Developers/stewards must show evidence that data elements are generated and used during routine care delivery, whether data elements are available in electronic health records (EHR) or will be available electronically within 1 year, and whether there is an implementable data collection strategy.

- **For maintenance:**
  - If measure specifications have changed, developers/stewards must discuss the extent to which those changes affect how data elements are generated and used, if the changes resulted in data elements not being available electronically, and how the changes affect the data collection strategy.
  - Developers/stewards must describe any challenges to measure implementation due to the data element and provide a mitigation strategy or a 1-year plan to overcome challenges identified.

Enhancements:

- **For initial endorsement:**
  - Person- or encounter-level empirical reliability and validity testing is required or prior empirical evidence to support that all critical data elements (numerator, denominator, exclusions) are reliable and valid.

- **For maintenance:**
  - Accountable entity-level empirical reliability and validity testing is required. Face validity testing alone is inadequate.*

Face validity testing at the accountable entity-level (i.e., measure score) is still accepted for initial endorsement.

Use & Usability

Enhancements:

- **Current or planned uses now include:**
  - Public reporting,
  - Public health/disease surveillance,
  - Payment programs,
  - Regulatory accreditation programs,
  - Professional certification or recognition programs,
  - Quality improvement with benchmarking, and
  - Quality improvement (internal to a specific organization).

Enhancements:

- **What is considered an accountability application?**
  - Accountability applications are uses of measure performance results about identifiable, accountable entities to make judgments and decisions because of performance. This can be as confidential reporting, reward, recognition, punishment, payment, or selection (e.g., public reporting, accreditation, performance-based payment, network inclusion/exclusion).

- **For initial endorsement:**
  - Developers/stewards must show evidence of a plan for use in at least one accountability application after initial endorsement and before the measure's first maintenance review.

- **For maintenance:**
  - If the measure is not currently in use in at least one accountability application, there must be a short-term plan (i.e., within 1 year) described.

5. PQM Measure Evaluation Rubric
Public Comments

Number of Comments

9

Summary

1. Battelle should consider updating the electronic clinical quality measure (eCQM) requirements, since the measure authoring tool is not longer available after June 2024.

2. Battelle should clarify whether data element validity for eCQMs is required only for critical data elements, or all data elements.

Number of Comments

9

Summary

3. Battelle should require reclassification error testing for measures used in public reporting.

4. Battelle should be consistent in use of terms such as "Person- or Encounter-Level Reliability" versus "data element reliability," and aligning with terms from the Blueprint.

5. PQM Measure Evaluation Rubric, *continued 2*
Public Comments

Number of Comments

9

Summary

5. Battelle should consider aligning fields and definitions in E&M submission form with the Measure Submission Form with corresponding fields within the Measures Under Consideration Entry/Review Information Tool (MERIT), where feasible.

6. Need for added guidance on how continuous variable measures should be entered, since they do not have a traditional numerator/denominator.

Number of Comments

9

Summary

7. Need to clarify the meaning of the deciles (e.g., deciles of reliability scores across providers or deciles of provider volume) for the accountable entity reliability distribution table.

8. For maintenance of endorsement, will there be an exception for face validity if there is justification for not being able to assess empiric validity? And consider applying a face validity threshold of 60% or greater.

Number of Comments

9

Summary

9. Battelle should consider requiring a distribution of measure scores (i.e., performance gap) for both initial endorsement and maintenance.

6. Added Types of Conditions for the "Endorsed with Conditions" Designation

Table 1. Types of conditions that can be placed on a measure

PQM Rubric Domain/Criterion	Condition(s)	Example
Importance	1. Conduct additional evaluation/assessment of meaningfulness to the patient community (e.g., patients, caregivers, advocates). 2. *[For maintenance]* Expand performance gap testing to a larger population.	1. Developer/steward has not, or to a limited degree, provided evidence from literature, focus groups, expert panels, etc. that the target population (e.g., patients) values the measured outcome, process, or structure and finds it meaningful for improving health and health care. 2. Maintenance measure has narrow gap, which may be due to limited data/testing within a population that may not be fully representative.
Reliability	1. Consider mitigation strategies to improve measure's reliability, such as increasing the case volume, including more than 1 year of data. For any facilities that are unable to exceed the threshold, give a rationale for why the reliability being below the threshold is acceptable for those specific facilities.	1. The developer/steward has performed measure score reliability testing (accountable entity-level reliability). Less than half of facilities did not meet the expected reliability value of 0.6.
Feasibility	1. Provide implementation guidance or a near-term path (within 1 year) for implementing the measure. This includes providing clear system requirements for implementation of the measure.	1. Measure has experienced or is projected to experience implementation challenges.
Use and Usability	1. Implement a systematic feedback approach to better understand if challenges exist with implementing the measure. 2. [For maintenance] Collect additional feedback from providers to ascertain the reasons why the measure is leveling off and describe appropriate mitigation approaches.	1. Measure has limited feedback due to low use and/or non-systematic feedback approach. 2. Trend data show a leveling off of measure performance.

6. "Endorsed with Conditions" Designation
Public Comments

Number of Comments

2

Summary

1. The committee should not endorse measures "with conditions" unless the conditions have been explicitly defined.

2. Need for greater clarity regarding the timeframe for the conditions to be met and suggest implementing a tiered approach, as not all conditions have equal weight.

7. Added Detail for Appeals Eligibility Criteria

- Appeal must cite evidence that the appellant's interests 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. The appeal must also include one of three rationales:

  1. Evidence exists 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 and is reasonably likely to affect the outcome of the original endorsement decision.

  2. The CBE's measure evaluation criteria were not applied appropriately. The appellant must specify the evaluation criterion that they believe was misapplied and why.

  3. The CBE executed a procedural error (i.e., CBE's E&M process was not followed). The appellant must specify the error/process step, how it was misapplied/not followed properly, and how this resulted in the measure being endorsed.

- In the case of a measure not being endorsed (new measure) or its endorsement removed (maintenance measure), the appeal must be based on one of two rationales:

  1. The CBE's measure evaluation criteria were not applied appropriately. The appellant must specify the evaluation criterion that they believe was misapplied and why.

  2. The CBE executed a procedural error (i.e., CBE's E&M process was not followed). The appellant must specify the error/process step, how it was misapplied/not followed properly, and how this resulted in the measure not being endorsed.

8. Clarifications to Endorsement Maintenance

- **Maintenance of endorsement encompasses several processes:**

  - Evaluations for endorsement maintenance,

  - Annual updates to measure specifications of endorsed measures,

  - Emergency/off-cycle reviews (i.e., early maintenance review), and

  - Education and technical assistance to measure developers on endorsement maintenance activities.

- **Maintenance requirements:**

  - Prior to 5-year maintenance review, at 3 years since the measure's endorsement, developers/stewards provide a **status report** indicating whether any changes to the measure specifications are needed or indicating that no changes are needed.

- **Measure deferment:**

  - Developers/stewards may request an extension of up to 1 year (two consecutive cycles), except if it has been more than 6 years since the measure's date of last endorsement.

#7-8. Appeals and Maintenance Requirements
Public Comments

Number of Comments

1

Summary

1. Battelle should note any deferrals/extensions in the Submission Tool and Repository.

2. Is the expansion of a measure's level of analysis considered to be the same measure that is to be assessed as part of maintenance review and not as a new measure submission?

Next Steps

Upcoming Engagement Opportunities

E&M Guidebook

- Final E&M Guidebook will be available by July 31, 2024 on the PQM website.

E&M Meetings

- **Spring 2024 Recommendation Group Meetings**:

  - July 26 – Primary Prevention

  - July 29 – Initial Recognition

  - July 30 – Management of Acute Events and Chronic Conditions

  - July 31 – Advanced Illness and Post-Acute Care

  - Aug 1 – Cost and Efficiency

Next E&M Cycle

- **Fall 2024**

  - Intent-to-Submit deadline is October 1, 2024

  - Full Measure Submission deadline is November 1, 2024

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Questions?

Contact us at p4qm.org/contact
or by emailing pqmsupport@battelle.org