Partnership for Quality Measurement

Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review (PRMR) and Measure Set Review (MSR)

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Executive Summary

The Pre-Rulemaking Measure Review (PRMR) Process is conducted yearly to provide recommendations to the Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS) on the selection of quality and efficiency measures under consideration for use by HHS. Similarly, the Measure Set Review (MSR) is conducted yearly to provide recommendations on the removal of measures from CMS programs. This Guidebook introduces a new process. It is organized to provide an overview of the PRMR and MSR policies and procedures and has been developed under Contract Number 75FCMC23C0010, titled, "National Consensus Development and Strategic Planning for Health Care Quality Measurement," sponsored by HHS CMS.

The Guidebook serves as a resource to all parties who are interested in these processes and includes details on the following:

1. PRMR and MSR activities, processes, and their associated timelines
2. Summary of committee compositions
3. Measure selection and removal criteria.

Figure 1 summarizes the activities and changes documented in this Guidebook. The policies and procedures reflect significant changes to the previously utilized process. Changes reflect a more integrated process of measure review, fewer committees, additional opportunity for public comment, and a higher degree of transparency. The Guidebook also provides an overview of the committee organization that supports the Novel Hybrid Delphi and Nominal Group (NHDNG) technique.[1] Battelle utilizes this multi-step process to increase engagement of all members and structure facilitation by using standard criteria and practices. The approach allows committees to maximize the value of the time spent to build consensus by focusing discussion on measures where there is disagreement. Committee members are made up of interested parties (formerly referred to as multi-stakeholder groups). Both PRMR and MSR use a modified version of this technique.[1]

[1] Davies S, Romano PS, Schmidt EM, Schultz E, Geppert JJ, McDonald KM. Assessment of a novel hybrid Delphi and Nominal Groups technique to evaluate quality indicators. Health Serv Res. 2011 Dec;46(6pt1):2005-18. doi: 10.1111/j.1475-6773.2011.01297.x. Epub 2011 Jul 25. PMID: 21790589; PMCID: PMC3393032.

Process Overview

PRMR: Process to seek input on the measures CMS is considering for use in specific CMS Medicare quality programs

MSR: Process to make recommendations about measures for potential removal

Building Recommendations

- Novel Hybrid Delphi and Nominal Group Technique
- Multi-step review ensuring rigor
- Meaningful opportunities for public engagement ensuring transparency
- Recommendations are evidence-based and quantifiable

Key Participants

- Diverse representation
- Emphasis on patients'/recipients of care and caregivers' voices
- Emphasis on under-represented voices
- Rural health and health equity expertise embedded into the committees reducing siloed discussions

What's New

- Coordinating Committee and advisory workgroups integrated into the setting-specific committees, resulting in fewer committees overall
- More time allocated for public comment period
- Listening session
- Integrated process
  - Smaller discussion groups emphasizing balanced perspective
  - All PRMR meetings scheduled in January

Figure 1: Overview of PRMR and MSR activities and recent changes.

Chapter 1. Pre-Rulemaking Measure Review & Measure Set Review

1.1 Overview

The goal of the Pre-Rulemaking Measure Review (PRMR) and Measure Set Review (MSR) processes is to inform the selection and removal of health care quality and efficiency measures, respectively, for use in Centers for Medicare & Medicaid Services (CMS) Medicare quality programs. Interested party input informs these recommendations. Effective engagement of interested parties is the cornerstone of a transparent and inclusive consensus-based process. The interested parties include those who are impacted by or are affected by the use of quality and efficiency measures. Interested parties include, but are not limited to, populations including patients/recipients of care and caregivers, clinicians, health care organizations, measure developers and stewards, as well as purchasers and health care plans.

This section provides an overview of how PRMR and MSR enable the Department of Health and Human Services (HHS) CMS to receive input on measure selection and retention.

1.1.1 Pre-Rulemaking Measure Review

The HHS, per statute,[2] publishes annually (by December 1) a list of measures under consideration (MUC) for future federal rulemaking. **The PRMR process makes consensus recommendations regarding the inclusion of measures being considered for CMS quality reporting and value-based programs**. In the context of a specific CMS program and population of Medicare beneficiaries (e.g., Skilled Nursing Facility Quality Reporting Program), the measure is appropriate for use if it is meaningful, tailored to unique needs, balanced and scaled to meet program-specific goals, and demonstrates a clear vision of near- and long-term program impacts.

Previously conducted via the Measure Applications Partnership (MAP) process, the annual review of measures under consideration is now called Pre-Rulemaking Measure Review (PRMR pronounced *Primer)*.

[2] Section 3014 of the Patient Protection and Affordable Care Act of 2010 (ACA) (P.L. 111-148) created section 1890A of the Social Security Act (the Act), which required HHS to establish a federal pre-rulemaking process for the selection of quality and efficiency measures for use by HHS.

1.1.2 Measure Set Review

MSR, another process enabled by statute,[3] centers on interested party reviews of measures across various CMS programs. The purpose of the MSR process is to optimize the CMS measure portfolio via measure removal recommendations.

The recommendations to remove a measure are based on updated information on the measure's properties, performance trends, and whether the measure continues to support the program's needs and priorities. **The MSR process builds consensus around measure removals to optimize the CMS measure portfolio in the quality reporting and value-based programs.**

The **PRMR process** makes consensus recommendations about measures on the MUC List.

The **MSR process** builds consensus around measure removals to optimize the CMS measure portfolio in the quality reporting and value-based programs.

1.1.3 PRMR and MSR Highlights

The PRMR and MSR processes are implemented through collaboration to balance the input of various interested parties, resulting in well-informed recommendations regarding measures to be included or removed from a specific CMS reporting program. PRMR's focus is on measures on the MUC List, each of which is targeted for a given program and population. PRMR assesses each measure's appropriateness for a specific intended use. In contrast, MSR entails a voluntary review of relative strengths and weaknesses of CMS's current measure portfolio and how the removal of an individual measure would reduce redundancy or create a measurement gap. The PRMR and MSR processes recommend selection or removal to address national health care priorities, fill critical measurement gaps, and increase alignment of measures among programs.

Table 1 summarizes the distinctions between these processes in terms of their overarching goals, approaches, and criteria for measure evaluation. Additional information on the evaluation criteria is in Appendix B.

[3] The Consolidated Appropriations Act (2021) granted the consensus-based entity the authority to provide input on the removal of quality and efficiency measures.
https://www.congress.gov/bill/116th-congress/house-bill/133/text

Table 1: Summary of PRMR and MSR scope and approach.

	Pre-Rulemaking Measure Review (PRMR)	Measure Set Review (MSR)
Goal	To achieve consensus regarding MUC list measures as to whether they are appropriate for CMS programs and target populations	To build consensus around measure removal recommendations through the identification of opportunities for optimization of the CMS measure portfolio
Requirement	Process required by statute on federal rulemaking process[2]	None, though the process is enabled by statute**Error! Bookmark not defined.**
Focus	Within targeted program and population (though in future cycles, the process may look across programs in the interest of alignment and burden reduction)	Across the entire CMS measure portfolio
Approach	Evaluate the appropriateness of each measure for a specific intended use	Evaluate purpose of measures in the context of the entire portfolio and how the purpose might best be achieved
Evaluation Criteria (Appendix B)	1. *Meaningfulness*: Measure is evaluated and tailored to unique needs of specific program-target population 2. *Appropriateness of scale*: measure portfolio is balanced and scaled to meet target program- and population-specific goals, specifically, measure is evaluated in the context of all the measures within the program measure portfolio *3.* *Time to value realization*: measure has plan for near- and long-term positive impacts on the targeted program and population as measure matures	1. *Impact*: Measure set evaluated across program, target population, and time 2. *Clinician data streams*: measure set redundancy in data streams is identified and mitigated, specifically by evaluating the burden associated with reporting the measure, considering other related measures *3.* *Patient journey*: measure set redundancy is identified and mitigated, specifically, by evaluating if the measure addresses the right aspect of care, in the right setting, and at the right point in a patient's journey to maximize the desired outcome

1.1.4 Annual PRMR and MSR Schedule and Adjusted Timeline for 2023

Figures 2 and 3 provide high-level schedules of selected annual PRMR and MSR activities. Other PRMR- and MSR-specific activities and meetings are scheduled as needed to meet CMS programmatic and statutory requirements. Figure 2 shows the timeline we will follow annually beginning in February 2024. The adjusted timeline shown in Figure 3 applies to the period from June 2023 to February 2024 and includes activities related to:

1. Committee member nominations
2. MSR process (internal assessments, public comment periods, and committee meetings)
3. PRMR process (internal assessments, public comment periods, listening session, and committee meetings)
4. Educational meetings (PRMR and MSR committee educational meetings, measure developers/stewards, CMS program leads, etc.).

In 2023, although there is a standard open call for nomination process for both PRMR and MSR, the timeframe for MSR recruitment is much shorter to accommodate the 2023 MSR process timeline.

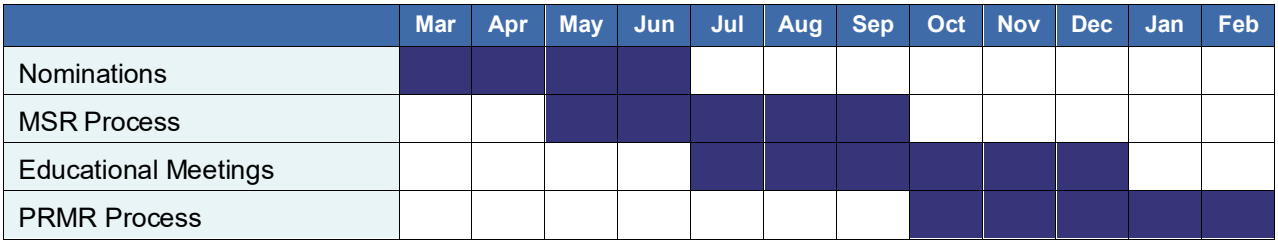


Figure 2: Standard Timeline of PRMR and MSR activities.

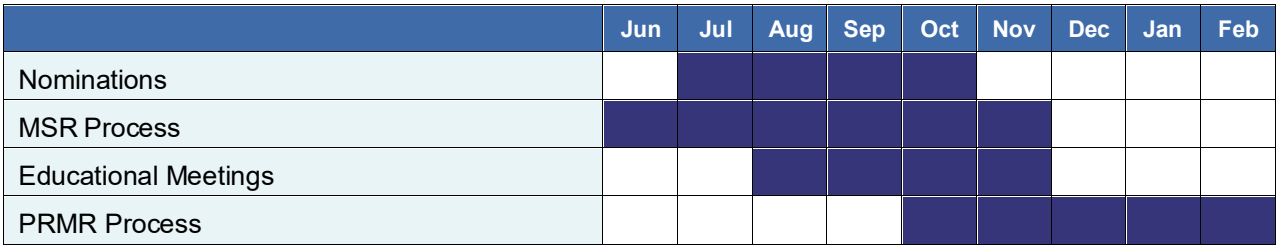


Figure 3: Adjusted timeline of activities, June 2023 to February 2024.

Chapter 2. Interested Party Organization

2.1 Overview

The Consensus-Based Entity (CBE, which is currently Battelle) convenes interested parties into committees to participate in PRMR and MSR. There are three PRMR committees—grouped by care setting (hospital, clinician, and post-acute care/long-term care). A select group of members from each of these committees will be tapped to participate in a single MSR committee that spans across care settings and populations. These committees consist of diverse members representing all facets of the health-care system. Battelle emphasizes the inclusion of patients/recipients of care, caregivers, patient advocates, and underrepresented minorities into the committee compositions. These members are organized in a manner best suited to provide input on measures needed for specific care settings, both within and across various CMS programs and patient populations. This committee structure supports the Novel Hybrid Delphi and Nominal Group (NHDNG), a multi-step hybrid technique that PRMR follows, which maximizes engagement of all members and structures facilitation by using standard criteria. MSR's recommendation group structure supports its modified NHDNG approach.

New process increases committee participation to up to **180** members.

2.2 Committee Nomination Process

Battelle staff conduct a review of committee member appointments annually, which includes internal re-calibration of the membership (i.e., assessment of committee rosters and identification of gaps in expertise among members to determine recruitment needs), a call for public nominations, and targeted outreach. A call for nominations is published on the Partnership for Quality Measurement (PQM) website and an announcement is sent to all PQM members. Nominations are submitted via the PQM website. Self-nominations are welcome. Third-party nominations must indicate that the organization or individual has been contacted and is willing to serve. Nominees will complete an application form and a Disclosure of Interest (DOI) form (Appendix A). Before finalizing the appointments, a draft roster of nominees is published on the PQM website to solicit public comment.

2.2.1 Committee Member Selection Criteria

To be eligible for participation, nominees should (1) have relevant expertise and demonstrated experience related to the use of quality and efficiency measures and/or (2) belong to at least one of the following categories:

1) Patients/recipients of care, caregivers, and patient advocates
2) Clinicians, including primary care providers and specialists
3) Facilities/institutions including accountable care organizations, hospitals or hospital systems, and post-acute/long-term care facilities
4) Clinician association

5) Facility association
6) Purchasers and plans (state, federal, and/or private)
7) Rural health experts
8) Health equity experts
9) Researchers in health services financing, alternative payment models (e.g., bundled payment, shared savings, all-payer models, etc.), population health, or implementation science methodology
10) Other Interested Parties (electronic health record [EHR] vendors, and experts in areas such as quality improvement/implementation science, care coordination, patient safety, behavioral health, and national policy makers).

Individual vs. Organizational Seats

While most PRMR committee members are individual appointments, certain roster categories are organizational. Organizations can self-identify their representatives.

Committees are made up of a combination of those who are the most impacted by adoption and implementation of the measures and those who bring broader and system perspectives to the PRMR and MSR processes.

Members of federal agencies also serve on the committees as non-voting federal liaisons. Federal liaisons do not go through the nominations and selection process. Instead, CMS, in collaboration with Battelle, identifies which federal agencies serve on the committees. They are invited to participate in the discussion to help provide context to measures and answer questions.

2.2.2 Time Commitment

Nominees commit to participating in scheduled calls and meeting dates, providing timely responses to requests for feedback, and being available for ad-hoc meetings and conference calls. Participation in PRMR and MSR activities entails all the following:

- Reviewing meeting materials prior to each scheduled meeting
- Attending and participating in virtual meetings
- Participating in meetings, as necessary. All review meetings are currently planned to be virtual, but there may be an opportunity for an annual in-person meeting
- Completing all surveys, pre-meeting assignments, and evaluations.

In the event a member cannot fulfill the above commitment, Battelle staff will contact the member to understand their challenges with fulfilling their commitment and may find a replacement. If a representative from a member organization is unable to fulfill their responsibilities prior to their term end, Battelle staff will contact the organization to find a replacement.

2.3 PRMR Committees

We use a cross-program approach when structuring PRMR committees to promote efficiency and alignment, reduce burden, and increase transparency. To those ends, we convene three overarching committees to provide input into measure reviews:

- Hospital and Hospital Related Facilities Committee
- Clinician Committee
- Post-Acute Care/Long-Term Care (PAC/LTC) Committee.

Committees provide recommendations directly to CMS.

These committees include a diverse membership of individuals from traditionally underrepresented groups such as patients/recipients of care and caregivers, people who belong to racial/ethnic minority groups, rural health providers, and experts in health disparities. Select PRMR committee members are invited to support MSR activities as well.

We welcome the critical expertise of patients/recipients of care and caregivers. To promote meaningful engagement, we conduct targeted orientations with patient and family committee members in advance of each meeting to familiarize them with the more technical aspects of the work and to affirm the importance of their participation in the group.

2.3.1 Hospital and Hospital Related Facilities Committee

The Hospital and Hospital Related Facilities Committee provides input on the selection of measures for hospital settings, including inpatient acute, outpatient, cancer, and psychiatric hospitals. The Hospital and Hospital Related Facilities Committee provides annual pre-rulemaking input related to the following programs:

- Ambulatory Surgical Center Quality Reporting Program (ASCQR)
- End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
- Hospital-Acquired Conditions Reduction Program (HACRP)
- Hospital Inpatient Quality Reporting (Hospital IQR Program)
- Hospital Outpatient Quality Reporting (Hospital OQR Program)
- Hospital Readmissions Reduction Program (HRRP)
- Hospital Value-Based Purchasing Program (HVBP)
- Inpatient Psychiatric Facility Quality Reporting Program (IPFQR)
- Medicare Promoting Interoperability Program (PI)
- Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program (PCHQR)
- Rural Emergency Hospital Quality Reporting Program (REHQR).

2.3.2 Clinician Committee

The Clinician Committee provides input on the selection of measures for clinicians' performance across CMS Medicare quality reporting and value-based programs. The Clinician Committee provides annual pre-rulemaking input related to the following programs:

- Medicare Part C and D Star Ratings
- Medicare Shared Savings Program (Shared Savings Program)
- Merit-based Incentive Payment System (MIPS) Program.

2.3.3 Post-Acute Care (PAC)/Long Term Care (LTC) Committee

The PAC/LTC Committee provides annual pre-rulemaking input related to the following programs:

- Home Health Quality Reporting Program (Home Health QRP)
- Hospice Quality Reporting Program (HQRP)
- Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP)
- Long-Term Care Hospital Quality Reporting Program (LTCH QRP)
- Skilled Nursing Facility Quality Reporting Program (SNF QRP)
- Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP).

2.3.4 Advisory and Recommendation Groups

Each committee includes two groups of reviewers—a Delphi group (hereafter referred to as an advisory group) and a nominal group (hereafter referred to as a recommendation group)—consistent with the principles of the NHDNG Technique (Figure 4). Detailed descriptions of the PRMR and MSR processes are included in Sections 3.3 and 3.4. MSR will be under the purview of a single recommendation group whose members are drawn from all three PRMR committees.

Advisory (Delphi) Group: Members in this group possess a system-level perspective. These include providers (clinicians & facilities), researchers, purchasers, and other interested parties (specialty societies, professional associations, EHR vendors, patient safety experts, quality improvement specialists, national policy makers, etc.). Members' participation includes providing written feedback during the PRMR process. Their feedback is foundational to the process of selection of a measure as part of the pre-rulemaking process.

Advisory Group input guides the Recommendation Groups' final consensus recommendations to CMS. Both groups work in tandem to provide meaningful impact on measures.

Recommendation (Nominal) Group: Members in this group are those who are most likely to be impacted by the implementation of quality measures. These include patients/recipients of care and caregivers, patient advocacy groups, providers (and facilities), health equity and rural health experts, and purchasers. Members' participation includes providing written feedback as well as participating in meetings.

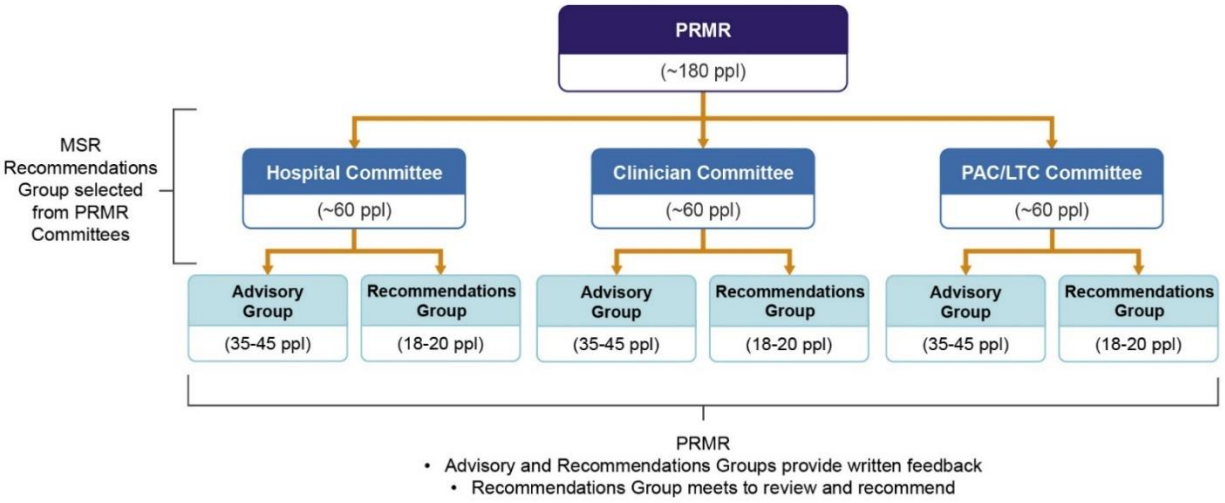


Figure 4: Organization of interested party committees.

To ensure representation of the population of interested parties, 60 members are recruited to the setting-specific committees, of which 35 to 45 are appointed to each advisory group. Each PRMR Recommendation Group will have 18 to 20 members. The MSR Recommendation Group is larger than the PRMR Recommendation Groups and includes 20 to 25 members. Battelle develops a roster for each setting-specific PRMR committee based on categories described in Section 2.2.1. Roster categories have both individual and organizational seats. There may be instances where two individuals from the same organization may serve on a committee while representing different categories within the same setting-specific committee.

NEW: Advisory Group vs. Recommendation Group

Battelle's PRMR and MSR committees are structured into an advisory group and a recommendation group. Members of the advisory group review and provide recommendations on measures prior to recommendation group meetings. These inputs ensure that a larger number of voices contribute to the consensus-building process.

The advisory and recommendation groups are mutually exclusive. recommendation group participants are randomly appointed on an annual rotational basis from the committee roster of eligible nominees, ensuring representation. For example, if our target is 7 "clinicians, including primary care providers and specialists" total, then, 2 of the 7 are randomly assigned to the recommendation group. The other 5 people will serve on the advisory group. We randomize appointments every year within a roster category, switching between the advisory and the recommendation groups. Randomization ensures fairness as well as allowing every committee member an opportunity to provide feedback through participation in both groups during their three-year rotation. If the appointed recommendation group member is unable to participate, then we still have enough eligible nominees in the category pool from which to draw additional members. A person will be on the advisory or recommendation group for an entire measure review cycle. Then for the next

cycle, assuming their term is still active, we will randomly select another member for the recommendation group. It is possible that someone who was on the advisory group for the previous cycle may be on the recommendation group for the next cycle.

On an as-needed basis, the membership of the recommendation group may be augmented with individuals with specialized expertise. For example, if a health care cost measure is under consideration for review, researchers and experts in health care financing may be invited to participate in the recommendation group if no one in the group has that expertise. These individuals serve as consultants to the recommendation group and are non-voting members.

Controlled randomization of advisory and recommendation groups increases transparency

2.3.5 Term of Appointment

A committee appointment is for a three-year term. In the 2023-2024 cycle, committee members will be randomly assigned term lengths of 1, 2, or 3 years to establish a rolling membership, allowing a third of the members to rotate off the committee annually. During their appointment, committee members will rotate on an as-needed basis between advisory and recommendation groups. In the event a member vacates their spot prior to their term end, Battelle will identify a replacement based on the vacated roster category. Organizations may replace their representatives as they choose to ensure consistent participation. The total length of the member term would not change. If individual committee members are unable to fulfill their terms (for any reason), their names would be removed from the roster during the annual nominations process and their seats potentially given to other experts. An incoming expert would serve a full three-year term.

During the three-year appointment, committee members will rotate between advisory and recommendation groups

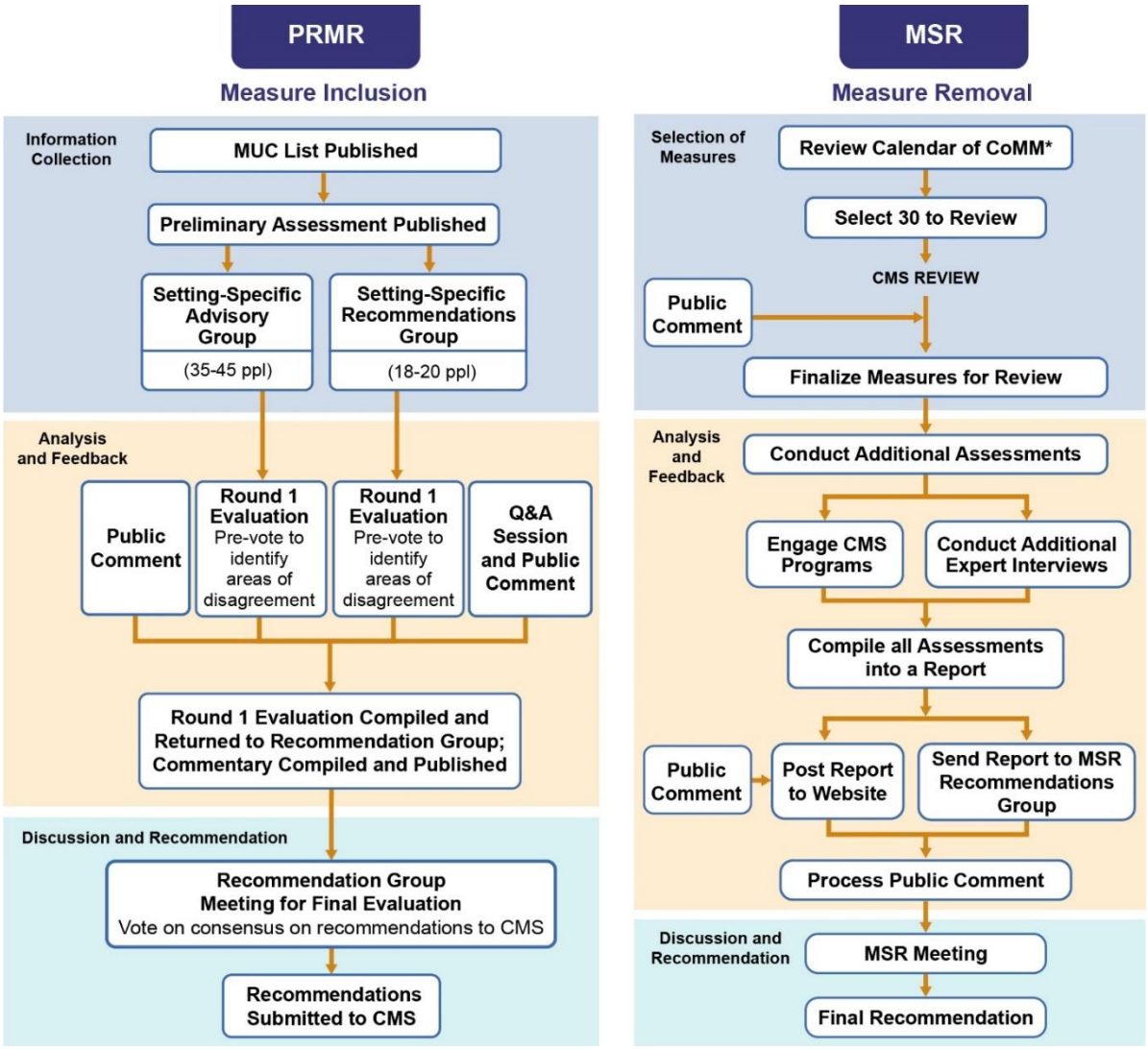
2.4 Interested Parties involved in MSR

PRMR committee members play a significant role in the MSR process as well. However, they are not organized in a setting-specific structure like PRMR. A select group of PRMR committee members are identified based on representation criteria for ensuring a range of voices within the group and invited to serve on the MSR Recommendation Group. The MSR Recommendation Group is larger than PRMR Recommendation Groups and includes 20 to 25 members and is inclusive of representatives from the three different settings (Hospital, Clinician, and PAC/LTC) included in the PRMR process. Members follow the three-year term similar to the appointment as the PRMR committees.

Chapter 3. PRMR and MSR Process and Evaluation

3.1 Overview

The PRMR and MSR evaluation processes entail iterative review of measures. The review process is a combination of Battelle-led assessments (Staff Assessments) and input from the committee members. Both evaluations use a multi-step process meant to increase engagement of all members and structure facilitation by using standard criteria and practices. However, there are some differences in the implementation of these processes. PRMR uses a modified NHDNG technique to build consensus among committee members, leveraging experienced and trained facilitators. The MSR process is less structured, to allow for a more holistic review involving qualitative assessment of portfolios of measures across programs and is guided by interested parties' input. Figure 5 presents an overview of these processes.



*CoMM: Cascade of Meaningful Measures.

Figure 5: PRMR and MSR Process Workflow.

3.2 Approach for Gathering Input

For PRMR, we solicit input through three methods tailored to the unique needs and engagement levels of interested party groups. Table 2 presents an overview of the approach for gathering input.

Table 2: Overview of the Approach for Gathering Input.

Interested Party Groups Engaged	Members	Format
Public comment	Unlimited	Open-ended
Advisory Group	35-45	Rubric ratings based on measure evaluation criteria
Recommendation Group	18-20	Rubric ratings based on measure evaluation criteria; Structured meeting guide

The approach for gathering input from select interested parties enables both structured and unstructured formats of information collection. The approach has built in levels of both broad and focused information gathering approaches and encourages diversity of input to the processes.

For MSR, we gather information via public comment periods and MSR Recommendation Group meetings, thus allowing for less structured, more holistic, and broader input into the process.

3.3 PRMR Process

Each PRMR cycle follows the steps outlined below:

1. MUC List is made available publicly December 1st of each calendar year.
2. In time for the December 1st MUC List release, staff develop Preliminary Assessment (PA) of the measures on the MUC List, which include review of each measure's scientific acceptability properties. These assessments involve (1) review of the information submitted through the CMS Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT), (2) discussion with measure stewards and developers, as needed, and (3) review of the PQM Submission Tool and Repository (STAR) database, as needed. This preliminary assessment determines whether a measure meets criteria related to importance, reliability, validity, feasibility, and usability in the context of its specific intended use. This allows the committee to focus its review on the PRMR goals—to assess if a measure is appropriate—rather than engaging in discussions better suited to the endorsement and maintenance (E&M) process. PAs are shared with PRMR committees during information collection.
3. Information Collection includes Round 1 Evaluation from advisory and recommendation groups and opportunity for public comment and listening sessions.
    a) Round 1 Evaluation: Upon the release of the MUC List on or before December 1, Battelle publicly disseminates a packet of information related to each measure on the MUC List, additional information on the measure information is in the Staff

Assessment section below. In addition to the packet of measure information, the advisory group and recommendation group of each PRMR committee receive guidance on the rubric ratings based on measure evaluation criteria for committee members.

b) Opportunity for public comment and listening sessions: A call for 21 days of public comment on the MUC List is issued concurrently with the MUC List release. Prior to the close of the public comment period, we host three public Listening Session, one per setting, where CMS, our staff, and measure developers/stewards address questions prior to the public submitting their comments and committee members submitting their ratings and explanations. Anyone can sign up for the session through the PQM website using an online form to give a brief verbal statement on one or more measures of their interest. Comments received during the public comment period and the Listening Session are compiled and posted on the PQM website within 5 days of the close of the public comment period.

Both the advisory and recommendation groups submit ratings and explanations of ratings on the measures (setting-specific).

4. Between public comment period and prior to the Recommendation Group meetings, staff compiles and synthesizes information collected from the public comment process, listening session, and written feedback from PRMR committees to aid the recommendation group meetings. Compiled comments and ratings from the advisory and recommendation groups are then used for determining areas of non-consensus for focus during the recommendation group meeting. A summary of the ratings and explanations from both these groups, along with compiled public comments are provided to the recommendation group to consider as they vote.

New Opportunity to Provide Feedback: Listening Session prior to committee meetings

5. Recommendation Group Meetings: In mid- to late-January, the recommendation group meets to discuss issues/concerns raised during the public comment period and feedback from the advisory group. Feedback from the advisory group is shared at least two weeks prior to the meeting and helps the recommendation group to prioritize their discussions on areas where consensus is lacking regarding the measure(s), based on the results from the pre-evaluation independent ratings. This is determined by the aggregated ratings from the first round from both groups. Battelle shares these first-round results with the recommendation group for review prior to the recommendation group meeting.

To increase efficiency, similar measures are discussed in a group. Recommendation group members then vote on the discussed measures individually. Once votes are tabulated for the grouped measures, the next set of grouped measures are discussed and voted on. More detail on the consensus and the voting process is provided in Chapter 4.

This iterative and graduated process of measure review improves efficiency and utilizes a meaningful approach for making final recommendations. Recommendation group meetings are facilitated by Battelle staff according to the compiled comments and ratings from the advisory and recommendation groups to ensure discussions remain productive, within scope, and inclusive of all voices. Battelle staff facilitate meetings, establish meeting ground rules and goals, conduct course corrections as needed, and ensure decisions are reached.

Recommendation groups meet in January of each calendar year to make final consensus recommendations to the CMS

Using a consensus threshold of 75%, Battelle's trained facilitators evaluate and communicate whether consensus was achieved, and dissenting views are noted in meeting summaries. This structured approach allows for efficient information exchange among committee members, which is particularly important when each member offers unique points of view.

3.4 MSR Process

Each MSR cycle follows steps outlined as below:

1. Review of Cascade of Meaningful Measures (CoMM) Priorities[4]

The Cascade of Meaningful Measures (CoMM) is a tool to help prioritize existing health care quality measures, align or reduce measures, and identify gaps where new measures may need to be developed. Every MSR cycle, Battelle proposes a set of measures across programs and populations within a select CoMM domain for review. Selection of a CoMM priority may be informed by conversations with key interested parties such as CMS and other national policy makers and through environmental scans from conferences and other national health care priority activities. This graduated approach manages the volume of measures under review for each cycle. The CoMM domains are Person-Centered Care, Safety, Chronic Conditions, Seamless Care Coordination, Equity, Affordability and Efficiency, Wellness and Prevention, and Behavioral Health.

[4] For the 2023 MSR process, Battelle will focus on a specific CMS Medicare quality program (e.g., End-Stage Renal Disease Quality Incentive Program) rather than a priority area from the Cascade of Meaningful Measures. This will allow us to pilot our consensus-building approach with the MSR committee through a lens that is more familiar to its members. In future years, we will shift to a more holistic approach as described in the narrative of this document.

2. Information Collection & Synthesis

Following this initial step, we post the initial set of selected measures for public comment for 15 days. Comments received are compiled, synthesized, and integrated into the internal measure review to develop a final set of measures for review.

Battelle engages CMS Program leads to gather programmatic performance data. As needed, Battelle also conducts an environmental scan, verifies information from the CMS MERIT system, conducts outreach with measure developers/stewards, and conducts ad-hoc interviews and focus group sessions with subject matter experts (SMEs) to inform the measure review process. Battelle synthesizes information collected from these different avenues to develop a report, which then is published on the PQM website for a second public comment period for 15 days. At least 3 weeks prior to the MSR Recommendation Group meeting, Battelle shares the report and compiled public comments with the group members.

3. Staff Assessments

For each MSR cycle, Battelle synthesizes information to guide the process. These assessments include:

a. Preliminary assessment: Battelle conducts a PA of measures including the following: (1) review of the information from CMS MERIT, if available; (2) discussion with measure stewards and developers to request any prior or updated testing data; (3) review of PQM STAR database if the measure was submitted for endorsement; and (4) programmatic performance data requested of CMS program leads. Battelle's review of each measure's scientific acceptability properties is based on the information collected through various methods as explained above. Battelle will also conduct ad-hoc expert interviews to solicit information on implementation in real-world settings. Battelle's PA, as discussed above, determines whether a measure is impactful, meaning it is found to be important, reliable, valid, feasible, and usable across programs and populations based on measure information and data provided. In addition, measures are reviewed against related or similar measures to identify redundancies related to data capture (e.g., where a lack of harmonization or alignment leads to data collection burden) or patient journey (e.g., where multiple measures address the same aspect of patient care). These reviews are based on the measure's purpose. PA results are shared with MSR Recommendation Group members.

b. Staff compile and synthesize information collected from both public comment periods to aid MSR Recommendation Group meetings.

4. Recommendation Group Meetings

The MSR Recommendation Group prioritizes discussion on measures with the least agreement based on comments received during both periods of public comment. Battelle's trained facilitators use established ground rules and goals for these

recommendation group meetings, conduct course corrections as needed, and ensure decisions are reached. Meeting goals and rules are shared at least 3 weeks prior to the meetings. Battelle summarizes the discussion from the meeting, including all dissenting views, and submits recommendations to CMS.

3.5 Evaluation Criteria

As described in Sections 3.3 and 3.4, our staff conduct PAs of measure properties in the context of each measure's intended use. These assessments generate evidence to support credibility of the measure properties.

PRMR assertions are based on evidence supporting meaningfulness, appropriateness of scale, and time to value realization. MSR assertions are based on evidence supporting the impact of the measure and how redundancies are addressed. Information on the measure properties drawn from STAR and CMS MERIT helps PRMR and MSR evaluate whether measures fulfill these measure evaluation criteria. In addition, measure developers and stewards are asked to provide supplemental information, such as any prior or updated testing data, specific to measure properties. Further information is available in Appendix B.

When committee members are presented with the Staff Assessments, they evaluate or rate the measures based on the evidence presented. PRMR and MSR criteria are intentionally open-ended to allow committees the opportunity to provide holistic feedback about measures under consideration for use in CMS programs. Battelle provides additional guidance to committees about how to apply each criterion (Appendix B). Committee members must specify and explain if they consulted additional evidence during their evaluation.

Committee members are asked to provide evidence rating for each criterion using the scale shown in Tables 3 (PRMR) and 4 (MSR):

1. Evidence is complete and adequate: Recommend.
2. Evidence is either incomplete or inadequate but there is a plausible path forward: Recommend with conditions.
3. Evidence is either incomplete or inadequate and there is no plausible path forward: Do not recommend.

Committee Evaluation Guidance

Appendix B includes more detailed information for committee members on how to appropriately apply each evaluation criterion to measures under review.

For PRMR, "recommend" means that the measure is recommended to the CMS for consideration to be added to a Medicare quality program. In MSR, "recommend" means that the measure meets all criteria and is recommended to be retained in the current CMS program.

Table 3: PRMR Criteria/Assertions (Intended use: specific program and population).

Criteria/Assertions	Evidence is complete and adequate	Evidence is either incomplete or inadequate but there is a plausible path forward	Evidence is either incomplete or inadequate and there is no plausible path forward
Meaningfulness: Importance, feasibility, scientific acceptability, and usability & use criteria met for measure considering the use across programs and populations			
Appropriateness of scale - Patients/ recipients of care: measure is implemented on patients/ recipients of care appropriate to the purpose of the program			
Appropriateness of scale - Entities: measure is implemented on entities appropriate to the purpose of the program			
Time to value realization: measure has plan for near- and long-term positive impacts on the targeted program- population as measure matures			
Overall	Recommend	Recommend with conditions	Do not recommend

Table 4: MSR Criteria/Assertions (Intended use: across programs and populations).

Criteria/Assertions	Evidence is complete and adequate	Evidence is either incomplete or inadequate but there is a plausible path forward	Evidence is either incomplete or inadequate and there is no plausible path forward
Impact: Importance, feasibility, scientific acceptability, and usability & use criteria met for measure considering the use across programs and populations			
Clinician data streams: measure redundancy in data streams has been identified and mitigated			
Patient journey: Measure is implemented across the patient journey as intended per the measure impact model			
Overall	Recommend	Recommend with conditions	Do not recommend (**Remove**)

3.6 Timeline

PRMR and MSR both utilize multi-step processes that span several months. The PRMR process entails a statutory requirement that starts on December 1 with the release of the MUC List and ends on February 1 of each year when the recommendations are submitted to CMS. In contrast, the MSR timeline is organized to best support CMS program leads in conducting program reviews following MSR recommendations. To accommodate the calendar of events, committee member appointments start in October of each calendar year and end in September of the following year. Figure 6 and Figure 7 provide overviews of PRMR and MSR activities and their associated timelines.

Month	Dec	Dec	Dec	Dec	Jan	Jan	Jan	Jan	Feb
Weeks	1	2	3	4	1	2	3	4	2
CMS releases MUC List; the public comments on MUC List	■	■	■						
PRMR committees provide written feedback	■	■	■						
CMS and Battelle host listening sessions to facilitate Q&A and public comment		■							
Battelle synthesizes feedback from public comment & committee evaluation			■	■	■				
Recommendation group meetings						■	■		
Battelle submits PRMR recommendations spreadsheet to CMS								■	

Figure 6: Overview of the PRMR activities and their associated timelines.

	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept
Battelle conducts internal review of the CoMM priorities to identify measures	■	■						
Public comments on measures initially identified for MSR review			■					
Battelle does measure evaluation (Specific outreach with CMS Program Leads, internal analyses, ad-hoc expert interviews)				■	■			
Battelle and CMS finalize list of measures for MSR review; develop a report					■			
Public comments on the report						■		
Measure Set Review: Recommendation Group Meeting							■	
Battelle submits final recommendations on MSR to CMS								■

Figure 7: Overview of the MSR activities and their associated timelines.

Chapter 4. Voting Procedures

4.1 Overview

Battelle conducts a multi-step process meant to increase engagement of all members and structure facilitation by using standard criteria and practices. The approach allows committees to maximize the value of the time spent by focusing discussion on measures (aspects of measures) where there is disagreement. Both the advisory and recommendation groups provide rubric ratings based on measure evlauation crtieria during Round 1 evaluation. Only the recommendation group casts final votes during the virtual measure review meeting to submit consensus recommendation to the CMS.

4.2 Establishing Consensus

Battelle utilizes the NHDNG multi-step process, an iterative consensus-building approach aimed at a minimum of 75% agreement among voting members, rather than a simple majority vote. Voting members are those who are appointed to the setting-specific recommendation groups. Consistent with our goal to add rigor to all aspects of the consensus development process, Battelle will rely on an evidence-based *consensus index* to determine whether consensus has been reached in committee votes. This index, analogous to the inter-rater reliability statistics, accounts for the degree of disagreement (or lack of consensus) in committee votes. This approach is advantageous in that it takes into consideration the different sizes of the voting groups and different ratings across groups. Based on this approach, consensus is determined to be 75% or higher agreement among members. Table 5 describes the consensus achievement process for final recommendations.

Table 5: Consensus Voting for Final Recommendations.

Recommend (A)	Recommend with Conditions (B)	Do not recommend (C)	Consensus Voting Status
More than 75%			A
	More than 75%		B
		More than 75%	C
75% or More			B
		25% to 75%	No consensus

The approach uses experienced facilitators (Battelle staff) who work with committee members to address areas of disagreement and the views of those in the voting minority, and to encourage

meaningful, inclusive discussions to establish more convincing consensus decisions. Iterative ratings as described in Sections 3.3 and 3.4 are used in addition to support the consensus process and to yield the final recommendation.

4.3 Quorum

Having a quorum for meeting attendance and voting is critical to ensure the discussion and the vote are robust and reflective of all perspectives represented in the group. The purpose of quorum is to ensure 1) we have enough participation for a robust discussion ("discussion quorum") and 2) we have enough participation to support the claim that the recommendation reflects the agreement of the community ("voting quorum"). Our discussion quorum threshold is 60%. Our voting quorum threshold is 80%. The discussion quorum is lower in part because of inconvenience and burden of having to reschedule meetings. Those who show up should be allowed to participate. In addition there are other sources of information to inform discussion (public comment, listening sessions). In the case of the voting quorum not being met, the remediation is to collect the votes for those present, not report out the results, and follow up with absent participants until a voting quorum is reached.

The discussion quorum requires the attendance of at least 60% of the recommendation group members at roll call at the beginning of the meeting. Battelle does extensive outreach ahead of the meetings to confirm quorum. In the event our communciations suggest we may not have quorum, Battelle will confirm back-up meeting dates.

The recommendation group members discuss measures in batches. That is, measures having similar concepts are grouped together. Following discussion on each of these batches of measures, voting occurs. This iterative process of grouping of measures, discussion, and voting ensures sufficient time is provided for each measure in the MUC List for discussion. The voting quorum is at least 80% of active committee members (recommendations group and advisory group), who have not been recused (see Chapter 6: Conflict of Interest Policy for more details). If the voting quorum is not met prior to voting, members that are present vote live during the meeting, but final votes will not be displayed. Those members not present at the meeting for voting will have until 48 hours (2 business days) after the meeting to vote offline.

We promote high attendance among voting members by engaging them early and often, including providing notice well in advance of scheduled meetings and sending detailed agendas and information packets for rating with sufficient time for review.

4.4 Facilitation

Effective and organized meeting facilitation ensures discussions remain productive, within scope, and inclusive of all voices. Trained facilitators (Battelle staff) have extensive experience facilitating committee meetings, webinars, and conference calls of comparable size and scope to PRMR and MSR committee meetings. Facilitators are responsible for establishing meeting ground rules and goals, keeping discussion on track, preventing discussions from being dominated by a small number of participants, and ensuring decisions are reached.

Chapter 5. Public Engagement

5.1 Overview

Public engagement activities play a crucial role in ensuring the processes for PRMR and MSR are transparent and bring diversity of voices into the process, which helps to ensure the integrity of the processes themselves. We welcome comments from all interested parties and look forward to comments from a wide range of diverse backgrounds. To promote accessibility, all public communication complies with Section 508. This section of the Guidebook describes methods for engaging the public (Section 5.2) and how the public can use the PQM website to keep informed of upcoming engagement opportunities (Section 5.3).

5.2 Methods of Engagement

Members of the public are invited to provide input on measures undergoing PRMR and MSR processes through the public comment process as well as during public meetings. Members of the public may also nominate committee members (Section 2.1).

1) Public comment process: There are several opportunities to provide input on measures undergoing PRMR and MSR processes via public comment. All public comment periods related to this work allow maximum time for members of the public to submit their input. Members of the public and PQM members can submit comments through the PQM website. PRMR has one public comment period (21 days), and MSR includes two public comment periods (15 days) (See Chapter 3). These steps for public engagement into both the PRMR and MSR processes are critical to ensuring rigor, transparency, and increased engagement.
2) Public Meetings: Members of the public may attend all PRMR and MSR committee meetings. Meeting information, including the meeting agenda and all associated meeting materials, are made available to the public via the PQM website at least 5 days ahead of scheduled meetings. The outcomes of the meetings, including meeting transcripts, meeting summaries, and PRMR and MSR final recommendation reports, are published on the PQM website following each meeting.
3) Nominations for committees: Committee nominations include an open call for nominations that is published on the PQM website. Draft rosters are published on the PQM website to solicit comments and further, those comments are included when final rosters of the committees are published. See Section 2.1 for details.

5.3 Modes of Communication

Battelle uses several communication tools, elaborated in the following sections, to engage interested parties throughout the PRMR and MSR cycles.

5.3.1 PQM Website

The PQM website will host all information relevant to upcoming opportunities for public and PQM member engagement as well as serving as the platform for public comment. The PQM website (Figure 8) enables users to connect with Battelle staff through a “Contact Us” form. Once a user completes the form, a pop-up informs the user their message has been sent and the user also receives an automated email acknowledging receipt. Users may also email Battelle staff directly at pqmsupport@battelle.org.

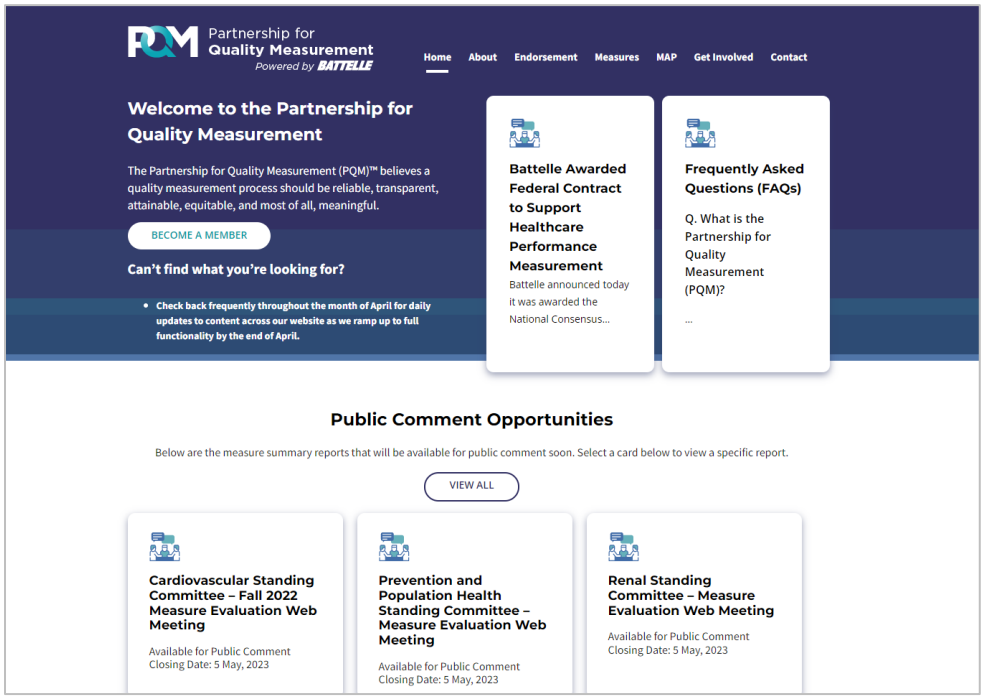


Figure 8: Screenshot of PQM Website www.p4qm.org.

All communications from the Contact Us form and PQM email inbox are routed to the PQM Support Desk via ServiceNow, a cloud-based platform for managing workflow and facilitating customer communications.

Through banners featuring the latest news, a calendar of events, and email notifications, the PQM website alerts interested parties of public comment periods specific to nomination and recruitment of interested parties for committees, public comment periods associated with PRMR and MSR cycles, upcoming public meetings, PRMR and MSR recommendations, and all general updates. Users may also access materials from current and past PRMR and MSR meetings, including meeting recordings, committee rosters, and meeting summaries.

5.3.2 Newsletter and Email Alerts

Updates on calls for nominations, public comment periods, committee meetings, meeting materials, and all status updates are also shared via newsletter and email alerts. Individuals may sign up for newsletters and email alerts through the PQM website.

Chapter 6. Conflict of Interest

Battelle applies its Conflict of Interest (COI) Policy (the "Policy") for all committee members to ensure the committee performs functions in a manner free from bias and undue influence. The term "conflict of interest" means any financial or other interest actual or perceived to (1) significantly impede the committee member's objectivity, or (2) create an unfair competitive advantage for the member or an organization associated with a relevant party. Disclosure of a financial interest does not automatically mean a COI exists but may warrant further discussion and review.

To complete the COI analysis, each member on a committee responsible for evaluating measures for providing recommendations for pre-rulemaking as well as measure removal will be required to complete an initial personal/organizational Disclosure of Interest (DOI) form (Appendix A) during the nomination process. In addition, committee members are asked to complete an additional "measure-specific DOI" form for each measure, or batch of measures, assigned to the committee. This latter form will contain questions relevant to the specific measure(s) being reviewed. Battelle will provide the measure-specific blank DOI form to committees at the start of each cycle. The form poses questions or prompts regarding members' financial interests and business associations that may present a perceived or actual COI.

By participating as a committee member, each member consents to public disclosure of general information about the members' financial or business interests, professional associations, and experiences of interest to the public regarding COI.

Measure-Specific COI

A member has directly and substantially contributed to the development of a measure or measures being considered for selection or removal.

The member or their spouse, domestic partner, or child could receive a direct financial benefit from a measure being recommended for selection or removal.

In the last 5 years, the member has received an indirect financial benefit, i.e., not related to the measure under review, of $10,000 or more from a measure developer whose measure is under review, or an indirect financial benefit of $10,000 or more, in the aggregate, from an organization or individual which may benefit from a measure being considered for the selection or removal process.

Member is currently employed by the measure developer and the developer has created the measure(s) under review, has created measure(s) in the topical area under review, or has created measure(s) that compete with measure(s) created by another developer and are under review.

If there is a perceived or actual COI, Battelle requires affected members to recuse themselves from the discussion and any voting regarding the applicable measure or measures, and in some instances, from discussion and

voting on competing and related measures. However, this does not prohibit the committee member from submitting public comments for the committee's considerations.

Additionally, committee members must orally disclose relevant interests at a public committee meeting. The disclosure usually occurs at a committee's first public meeting. Senior Battelle staff will lead this disclosure and instruct committee members regarding information that should be disclosed. Following oral disclosure by committee members, Battelle program staff will invite committee members to ask questions of each other or Battelle staff regarding any disclosures made by committee members.

Finally, all committee members have an ongoing duty to monitor for COI issues of themselves and fellow committee members and raise or disclose any issues either in a committee meeting, to the committee chair, the Battelle program team, or the Battelle legal department. Committee members should take a proactive approach and report any instances if a fellow committee member appears conflicted or is acting in a biased manner.

Appendix A. Disclosure of Interest Form

PERSONAL/ORGANIZATIONAL DISCLOSURE OF INTEREST FORM

1. Your Name:

   Your Organization Affiliation:

   Committee Name:

Describe any personal or organizational relationships subject to disclosure.(e.g., disclosures may include relationships with employees of organizations developing or stewarding the measure, stock options in companies that may benefit from the measures)

2. If None, check here: ☐

3. Describe any personal or organizational financial interests subject to disclosure. If None, check here: ☐

4. Electronic Certification
   By executing this Electronic Certification, I certify that I have reviewed the Personal/Organizational Disclosure of Interest Form, and the information given above is true to the best of my knowledge.

Name: _____ **Signature:** _____

Date: _____

You and all other persons and organizations must be free of any conflicts of interest for this effort. If at any time you believe that a potential or actual conflict exists, you must notify Battelle immediately. "Conflict of Interest" means because of other activities or relationships with other persons or organizations you are unable or potentially unable to (1) render impartial assistance or advice; (2) perform due to the impairment of or the possibility of the impairment of your objectivity; or (3) perform because you have or might acquire an unfair competitive advantage.

Appendix B. Supplemental Guidance on Applying PRMR and MSR Criteria

PRMR and MSR criteria are intentionally open-ended to allow committees the opportunity to provide holistic feedback about measures under consideration for use in CMS Medicare quality programs. However, we will provide additional guidance to committees about how to apply each criterion. Below we describe some prompts and considerations we could share with committee members to aid in their review:

PRMR Criteria

- **Meaningfulness**: Has it been demonstrated that this measure meets criteria associated with importance, scientific acceptability, feasibility, usability, and use for the target population and entities of the program under consideration? If the endorsement has been removed, reviewers will need to consider the reasons for removal when making this determination. And for measures that have not undergone E&M review, Battelle staff will provide a brief assessment summarizing the extent to which these criteria have been demonstrated (Note: This is not intended to replace CBE E&M Review.) Does this measure address a high-impact clinical and/or policy area? Will progress in this measure demonstrably improve care for the intended population? Does this measure support best care for all individuals equitably? Do any potential unintended consequences preclude use of this measure?

- **Appropriateness of scale**: How is implementation of the measure applied to optimize the measure value across segments of the target population and entities of the program under consideration? Reviewer considerations may include prevalence of the measure focus or likely impact of quality improvement in response to measurement. Are there other or complementary strategies for quality improvement that might supplement measurement for certain segments of the target population or entities? Patient and Caregiver Impact: The measure is meaningful to patients/caregivers and produces information that is valuable to them in making their care decisions. Appropriateness: The measure is appropriate for the program(s) for which it is recommended. Equity: The measure may identify an equity gap or is able to be stratified to determine difference in care in vulnerable patients.

- **Time to value realization**: To what extent does current evidence suggest a clear pathway from measurement to performance improvement? How might measurement support the generation of better evidence in the future? How might that evidence mature over time to reduce uncertainty about how entities may best improve outcomes? National Impact: the measure meets a significant national quality/safety issue, and the use of this measure would improve overall care practices and outcomes. Interoperability: the measure includes standardized data elements as identified in U.S. Core Data for Interoperability (USCDI) or USCDI+ (version 3). Is this measure digital, or does it have

the capability of being transitioned into a digital format? Do the data elements of this measure align with USCDI/USCDI+ standard definitions?

MSR Criteria

- **Impact**: Is the measure CBE-endorsed? If not endorsed, are the E&M criteria met for the measure, considering the use across programs and populations? If the endorsement has been removed, reviewers will need to consider the reasons for removal when making this determination. For measures that have not undergone E&M review, Battelle staff will provide a brief assessment summarizing the extent to which these criteria have been demonstrated (Note: This is not intended to replace CBE E&M Review.) Appropriateness: The measure is appropriate for the program(s) for which it is recommended. Equity: The measure may identify an equity gap or is able to be stratified to determine difference in care in vulnerable patients.

- **Clinician data streams**: How burdensome is this measure to report, considering other related measures? Has the measure been harmonized with similar measures to reduce reporting burden associated with the existence of related/redundant measures? To what extent does the impact of this measure outweigh the burden associated with reporting on it?

- **Patient journey**: Consider the patient journey, from screening or initial presentation of symptoms, through diagnosis, treatment, and outcomes. Does the measure address the right aspect of care, in the right setting, and at the right point in the patient's journey to maximize the desired outcome? To what extent does the measure address an aspect of care that is otherwise missing from the measure portfolio? Patient and Caregiver Impact: the measure is meaningful to patients/caregivers and is information that is valuable to them in making their care decisions.

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