



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 processes and incorporates changes as suggested by interested parties through a public comment period. Appendix C provides a discussion of the comments. This Guidebook is updated on an annual basis, all proposed changes will undergo a public comment period.

The Guidebook 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 NHDNG technique.

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.



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. These 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

HHS, per statute,² publishes annually (by December 1) a list of measures under consideration (MUC) for future federal rulemaking. **The PRMR process supports consensus recommendations regarding the inclusion of measures for consideration 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 **PRMR process** makes consensus recommendations about measures on the MUC List.

1.1.3 PRMR and MSR Highlights

The PRMR and MSR processes are implemented to foster collaboration and 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 responsibility is to assess the appropriateness of the specific intended use of the measures included on the MUC List, each of which is targeted for a given program and population. In contrast, MSR conducts 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.



The **MSR process** builds consensus around measure removals to optimize the CMS measure portfolio in the quality reporting and value-based 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 Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, 134 Stat. 1182 (2020). 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	None, though the process is enabled by statute
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 program portfolio and how the purpose might best be achieved
Evaluation Criteria (Appendix B)	<ol style="list-style-type: none"> <i>Meaningfulness</i>: Measure is evaluated and tailored to unique needs of specific program-target population <i>Appropriateness of scale</i>: 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 currently within the program measure portfolio <i>Time to value realization</i>: measure has plan for near- and long-term positive impacts on the targeted program and population as measure matures 	<ol style="list-style-type: none"> <i>Impact</i>: Measure set evaluated across program, target population, and time <i>Clinician data streams</i>: measure set redundancy in data streams is identified and mitigated, specifically by evaluating the burden associated with reporting the measure, considering other related measures <i>Patient journey</i>: 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 annual timeline 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:

- Committee member nominations

- MSR process (internal assessments, public comment periods, and committee meetings)
- PRMR process (internal assessments, public comment periods, listening session, and committee meetings)
- Educational meetings (PRMR and MSR committee educational meetings, measure developers/stewards, CMS program/measure leads, etc.)

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

	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Nominations												
MSR Process ⁴												
Educational Meetings												
PRMR Process												

Figure 2: Standard Timeline of PRMR and MSR activities.

	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Nominations									
MSR Process									
Educational Meetings									
PRMR Process									

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

⁴ MSR timeline is subject to change.

Chapter 2. Interested Party Organization

2.1 Overview

The Consensus-Based Entity (CBE, which is currently Battelle) created the Partnership for Quality Measurement (PQM) by bringing together members from across the health care and quality landscape who are interested in promoting meaningful quality measurement. 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 spanning 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 uses, 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 [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 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](#)). Battelle will prioritize selection of individuals who have participated in similar panels/committees in the past or can demonstrate knowledge of these processes; fit into more than one roster category (discussed in detail in Section 2.2.1); and possess lived experience interacting with the health care system. We will balance this with the need to include under-represented voices, which may include individuals with relevant background and experience but who have not had an opportunity to participate in these processes before. Battelle’s goal is to create committees inclusive of the roster categories, with a balance of experience, expertise, and perspectives.

Once appointed, all committee members will attest to a Measure DOI form ([Appendix A](#)) at the start of each PRMR or MSR review process. Before finalizing the appointments, a draft roster of nominees is published on the PQM website to solicit public comment.

2.2.1 Committee Member Roster Categories

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 roster categories:

- Patients/recipients of care, caregivers, and patient advocates
- Clinicians (for example primary care providers and specialists, dentists, nurses, pharmacists, physio and occupational therapists and other health care professionals)
- Facilities/institutions (for example, accountable care organizations, hospitals or hospital systems, and post-acute/long-term care facilities)
- Clinician association
- Facility association
- Purchasers and plans (state, federal, and/or private)
- Rural health experts
- Health equity experts
- Researchers in health services financing, alternative payment models (e.g., bundled payment, shared savings, all-payer models), population health, or implementation science methodology
- 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. The committee membership is made up of both individual and organizational seats. The committee roster categories are listed in Table 2.

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. Federal liaisons 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

For each PRMR cycle (1 per year) the time commitment is about 40-60 hours, which includes:

- Orientation meeting⁵
- Two days of virtual meetings for measure review (10 am - 5 pm ET) if appointed to the recommendation groups
- Assessment of the measures under consideration for that PRMR cycle
- Review of meeting materials in advance of the all-day review meeting
- Answer emails requesting availability or other requests

For each MSR cycle (1 per year), the time commitment is about 20 hours, which includes:

- Orientation meeting⁵
- One all-day in-person meeting for measure review (8:30 am- 5.30 pm ET)
- Review meeting materials in advance of the all-day review meeting
- Answer emails requesting availability or other requests

In the event a member cannot fulfill the 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

Battelle uses a cross-setting 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.

⁵ In 2023, Battelle will convene one all-day, in-person orientation meeting (8:30 am – 5pm ET).

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. Honoraria may be available for patients/recipients of care and caregivers based on need.



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:

- 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:

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



2.3.3 PAC/LTC Committee

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

- Home Health Quality Reporting Program (Home Health QRP)
- Hospice Quality Reporting Program (HGRP)
- 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' participation includes providing written feedback during the PRMR process. Their feedback is foundational to the recommendation process as part of the pre-rulemaking process.

Recommendation (Nominal) Group: Members' participation includes providing written feedback as well as attending measure review meetings.

Recommendation Group Co-Chairs: Recommendation group meetings are facilitated by Battelle staff and two recommendation group members designated as co-chairs.

Selected on an annual basis, one co-chair will be a patient representative and the other co-chair will represent one of the remaining recommendation group roster categories. The role of the co-chairs is to:

- Co-facilitate meetings, along with Battelle staff to ensure discussion is inclusive of advisory group and public comments.
- Work with Battelle staff to achieve the goals of the recommendation group meetings.
- Assist Battelle staff in anticipating questions and identifying additional information that may be useful to the recommendation group.
- Oversee the appointment of subject matter experts (SME) as non-voting members of the committee to augment the committee discussions.
- Participate as a full voting member.

Advisory Group input guides the recommendation groups' final consensus recommendations to CMS. Both groups work in tandem to provide meaningful input on the selection of measures.

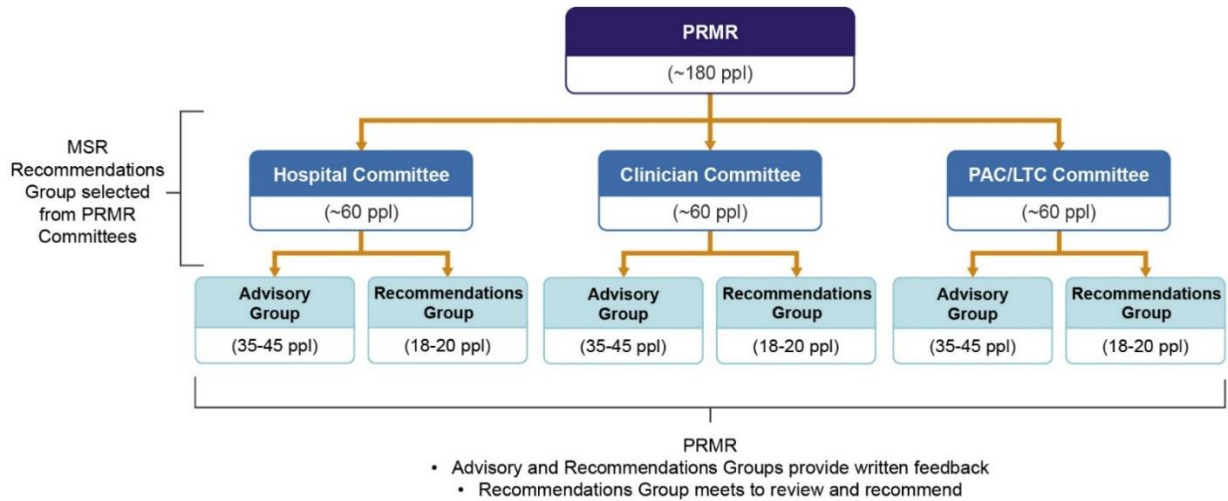


Figure 4: Organization of interested party committees.

To ensure representation of the population of interested parties, approximately 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 as depicted in Table 2. 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.

Table 2: Roster Categories and Target Number of Individuals for PRMR and MSR.

Roster Category	PRMR Advisory Group Targets	PRMR Recommendation Group Targets	MSR Recommendation Group Targets
Patients/ recipients of care, families, caregivers, patient advocates	5	2	3
Clinicians, including primary care providers and specialists	5	2	3
Facility Association	3	2	3
Clinician Association	3	2	3
Facilities/institutions including accountable care organizations, hospitals or hospital systems, and post-acute/long-term care facilities	7	4	3
Purchasers and plans (state, federal, and/or private)	3	2	2
Persons that have experience with rural health (e.g., providers, patients/ recipients of care, researchers)	3	1	1
Persons that have experience with health equity (e.g., providers, patients/ recipients of care, researchers)	3	1	1
Researchers in health services, alternative payment models, population health	5	2	2
Other Interested Parties EHR vendors, and experts in areas such as quality improvement/ implementation science, care coordination, patient safety, behavioral health, and national policy makers)	5	2	2
Federal Liaisons (non-voting)	TBD	TBD	TBD
TOTAL	42	20	23
Range	(35 – 45)	(18 – 20)	(20-25)

2.3.5 Appointment to the Advisory and Recommendation Groups and Term Length

To ensure fairness to the process, Battelle will instill a process of randomization of assignments to groups and term limits. 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 the target is seven “clinicians, including primary care providers and specialists” total, then, two of the seven are randomly assigned to the recommendation group. The other five people will serve on the advisory group. A committee appointment is for a 3-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. The process of random assignment will be:

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.

1. *Step 1:* Within each roster category, identify the pool of eligible nominees.
2. *Step 2:* Among eligible nominees, randomly select participants into 1-, 2-, or 3-year terms.
3. *Step 3:* Among participants, allocate by schedule to advisory or recommendations group.

Controlled randomization of advisory and recommendation groups increases transparency

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 3-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. All committee members will get an opportunity to participate at least once in the recommendation group in their 3-year term. In 2023, those appointed to term lengths of 1 or 2 years will be eligible to reapply for the committees after their term ends and be considered into the recommendation group appointment.

During the 3-year appointment, committee members will rotate 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 3-year term.

2.3.6 Appointment Subject Matter Experts

On an as-needed basis, the membership of the recommendation group may be augmented with individuals with specialized expertise to serve as non-voting members of the committee. 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. The process of recruitment of these experts is guided by the MUC review and measures under review for the MSR cycle. For example, following preliminary staff reviews of MUC list measures, Battelle staff will note any specific clinical expertise that may be needed to evaluate each measure. If that expertise is not currently represented in the PRMR roster, Battelle will work with the committee co-chairs to identify the criteria for a potential SME. Based on that, Battelle will identify potential candidates from among PQM members and their networks. All SMEs will be required to provide disclosure statements prior to any meeting, which will be made public.

2.4 Interested Parties involved in MSR

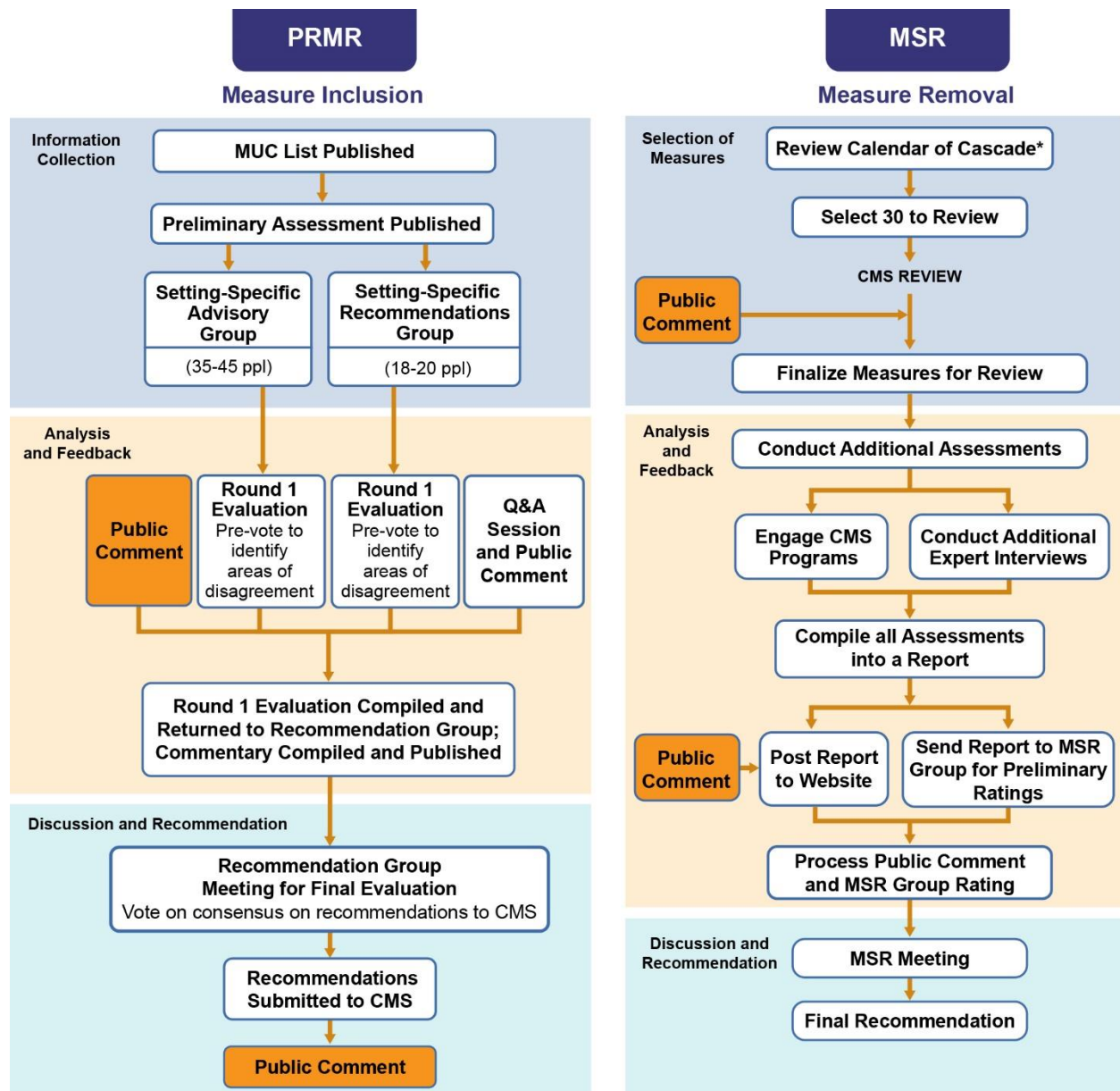
PRMR committee members play a significant role in the MSR process as well. A select group of PRMR committee members are identified and invited to serve on the MSR Recommendation Group. MSR Recommendation Group appointment is on an annual basis and membership is guided by the type of measures under review for each MSR cycle. Members appointed to a given MSR cycle have more opportunities to provide feedback by participating in both the MSR and the PRMR processes. 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) in the PRMR process. Additional information on MSR schedule is available in Chapter 3.

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 (Preliminary 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.



*Cascade: Cascade of Meaningful Measures.

Figure 5: PRMR and MSR Process Workflow.

3.2 Approach for Gathering Input

For PRMR, Battelle solicits input through three methods tailored to the unique needs and engagement levels of interested party groups. Table 3 presents an overview of the approach for gathering input.

Table 3: Overview of the Approach for Gathering Input.

Interested Party Groups Engaged	Members	Format
Public comment	Unlimited	Open-ended
Advisory Group	35-45	Feedback on assertions made on each measure
Recommendation Group	18-20	Feedback on assertions made on each measure; 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 and timeline specified in Figure 6:

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 Assessments (PAs) of the measures on the MUC List. The PAs includes review of each measure's scientific acceptability properties. These assessments involve review of the information submitted through the CMS Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT); discussion with measure stewards and developers, as needed; and review of the PQM Submission Tool and Repository (STAR) database, as needed. This PA 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.
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 the PA related to each measure on the MUC List. In addition to the PAs, the advisory group and recommendation group of each PRMR committee also receive guidance on the providing feedback on the assertions on

each measure. Both advisory and recommendation group members review the evidence presented in the PAs to submit initial feedback on the measures.

- 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, Battelle 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 made publicly available 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. 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 feedback 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 feedback from both groups, along with compiled public comments are provided to the recommendation group to consider as they vote. Results of the Round 1 Evaluation from the PRMR committees are only shared with the recommendation group.

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. Results of the round 1 evaluation are shared with the recommendation group at least two weeks prior to the meeting. This helps the recommendation group to prioritize their discussions on areas where consensus is lacking regarding the measure(s), based on the results from the round 1 evaluation.

Meeting Procedure: Each setting-specific recommendation group meets virtually for one or two full days (depending upon the number of measures under review) in mid-January. The meetings are open to the public. The meeting procedures are:

Step 1: Battelle staff will review the PA for each MUC using the PRMR criteria, including summarizing the results of the round 1 evaluation, public comment, comments from the listening sessions and programmatic objectives.

Step 2. A CMS representative will present a brief overview and/or contextual background on the MUC.

Step 3: Battelle, as the lead facilitator, along with co-chairs then open for the recommendation group discussion. Similar measures (such as those that address a Cascade of Meaningful Measures priority area like “safety” measures) are discussed consecutively. CMS staff, Battelle facilitators, co-chairs, and measure developers will respond to the clarifying questions on the PA and the specifications of the measure, as necessary.

Step 4: Meeting facilitators request members of the public to submit their comments via virtual meeting platform. Anyone can sign up for the meeting through the PQM website using an online form to give a brief verbal statement on the measure or measures being discussed.

Step 5: Recommendation group members then vote on the discussed measures individually. 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 who work with co-chairs to ensure discussions remain productive, within scope, and inclusive of all voices. Battelle staff, along with co-chairs, establish meeting ground rules and goals, conduct course corrections as needed, and ensure decisions are reached.

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.

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

6. Second public comment opportunity: Final recommendations from the recommendation groups are published on February 1 of each year on the PQM website for 15 days for a second public comment period. The intent of this opportunity is to provide additional feedback on MUC and the final recommendations to CMS.

3.4 MSR Process

Each MSR cycle follows steps outlined:

Step 1: Review of Cascade of Meaningful Measures (Cascade) Priorities⁶

The [Cascade of Meaningful Measures \(Cascade\)](#) is a tool to help prioritize existing health care quality measures, to align or reduce the number of 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 Cascade domain for review. Selection of a Cascade priority may be informed by conversations with key interested parties such as PRMR committee members, 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 Cascade domains are Person-Centered Care, Safety, Chronic Conditions, Seamless Care Coordination, Equity, Affordability and Efficiency, Wellness and Prevention, and Behavioral Health.

Step 2: Information Collection & Synthesis

Battelle posts 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 conducts a PA of the final set of measures including review of the information from CMS MERIT, if available; discussion with measure stewards and developers to request any prior or updated testing data; review of PQM STAR database if the measure was submitted for endorsement; and programmatic performance data requested of CMS program/measure 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 previously discussed, 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. Battelle synthesizes information collected from these

⁶ 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.

different avenues to develop a report, which then is published on the PQM website for a second public comment period for 15 days.

Step 3: Recommendation Group Meetings Round 1 Evaluation

Battelle shares the draft report with the MSR Recommendation Group along with guidance on the rubric ratings based on measure evaluation criteria. The purpose of this round 1 evaluation is to determine where there is the most disagreement among members and to focus discussion during the meeting on these measures.

Battelle staff compiles and synthesizes information collected from the public comment process and round 1 evaluation to aid the MSR Recommendation Group meeting. Compiled comments and ratings 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.

Step 4: Recommendation Group Meetings

The MSR Recommendation Group prioritizes discussion on measures with the least agreement based on round 1 evaluation as well as comments received during both periods of public comment.

Meeting Procedure: The MSR Recommendation group meets virtually for one or two full days (depending upon the number of measures for review). The meetings are open to the public. The meeting procedures are:

Step 1: Battelle staff will review the PA for each measure using the PRMR criteria, including summarizing the results of the round 1 evaluation, public comment, and programmatic objectives.

Step 2: A CMS representative will present a brief overview and/or contextual background on the measure or measures under review.

Step 3: Battelle as the lead facilitator, along with co-chairs, then call on the recommendation group for discussion. CMS staff, Battelle staff, and measure developers will respond to the clarifying questions on the PA and the specifications of the measure, as necessary.

Step 4: Next, meeting facilitators request members of the public to submit their comments via a virtual meeting platform. Anyone can sign up for the meeting through the PQM website using an online form to give a brief verbal statement on the measure or measures of their interest being discussed.

Step 5: Recommendation group members then vote on the discussed measures individually. Once votes for the measures are tabulated, the next measure is discussed and voted on.

This iterative and graduated process of measure review improves efficiency and utilizes a meaningful approach for making final recommendations. Battelle staff and co-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 Measure Evaluation

As described in Sections 3.3 and 3.4, Battelle 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 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 PAs, they evaluate 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 feedback using the scale shown in Tables 4 (PRMR) and 6 (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 review measures under review.

For PRMR, “recommend” means the measure is recommended to CMS for consideration to be added to a Medicare quality program (Table 5). In MSR, “recommend” means the measure meets all criteria and is recommended to be retained in the current CMS program (Table 7).

Table 4: PRMR 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
<i>Meaningfulness</i> : Importance, feasibility, scientific acceptability, and usability & use criteria met for measure considering the use across programs and populations			
<i>Appropriateness of scale - Patients/ recipients of care</i> : measure is implemented on patients/ recipients of care appropriate to the purpose of the program			
<i>Appropriateness of scale - Entities</i> : measure is implemented on entities appropriate to the purpose of the program			
<i>Time to value realization</i> : measure has plan for near- and long-term positive impacts on the targeted program-population as measure matures			

Table 5: Overall recommendation of the Measure Under Consideration for the designated CMS Medicare quality program.

Overall	Recommend	Recommend with conditions (Please specify the conditions)	Do not recommend
Measure under consideration			

Table 6: MSR Criteria/Assertions (Intended use: across programs and populations). Error! Bookmark not defined.

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
<i>Impact:</i> Importance, feasibility, scientific acceptability, and usability & use criteria met for measure considering the use across programs and populations			
<i>Clinician data streams:</i> measure redundancy in data streams has been identified and mitigated			
<i>Patient journey:</i> Measure is implemented across the patient journey as intended per the measure impact model			

Table 7: Overall recommendation of the measure to be retained or removed from the designated CMS quality program.

Overall	Recommend	Do not recommend
Measure under review		

3.6 Timeline

PRMR and MSR both utilize multi-step processes spanning several months. The PRMR process entails a statutory requirement starting 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/measure 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. The MSR timeline is subject to change in future cycles. 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	1
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 Cascade priorities to identify measures								
Public comments on measures initially identified for MSR review								
Battelle does measure evaluation (specific outreach with CMS program/measure 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 feedback 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. 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. Consensus status can be A (recommend), B (recommend with conditions) or C (do not recommend). Table 8 describes the consensus achievement process for final recommendations.

Table 8: Consensus Voting for Final Recommendations.

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

The approach uses experienced facilitators (Battelle staff) who work with co-chairs 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 a quorum is to ensure we have enough participation for a robust discussion (“discussion quorum”) and we have enough participation to support the claim that the recommendation reflects the agreement of the community (“voting quorum”).

Discussion quorum: The discussion quorum requires the attendance of at least 60% of the recommendation group members at roll call at the beginning of the meeting. If there is less than 60% attendance, then the Recommendation Group will not discuss the measures and a back-up meeting will be held. Battelle will do extensive outreach ahead of the meetings to confirm quorum will be achieved.

Voting quorum: The voting quorum requires at least 80% of active recommendation group members, who have not been recused (see Chapter 6: Conflict of Interest Policy for more details). A higher voting quorum ensures representation of the community in the consensus agreement. 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. If quorum is not reached, recommendation of “no consensus” is submitted to the CMS.

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. Battelle staff have extensive experience facilitating committee meetings, webinars, and conference calls of comparable size and scope to PRMR and MSR committee meetings. Battelle staff will work with co-chairs to establish 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. Battelle welcomes comments from all interested parties and looks 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 and listening sessions. These opportunities 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 two public comment periods: one is for 21 days to solicit feedback to the MUC List and the other for 15 days after the recommendations are finalized. PRMR process also has setting-specific listening sessions in December of each calendar year. 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 recommendation group 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 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.

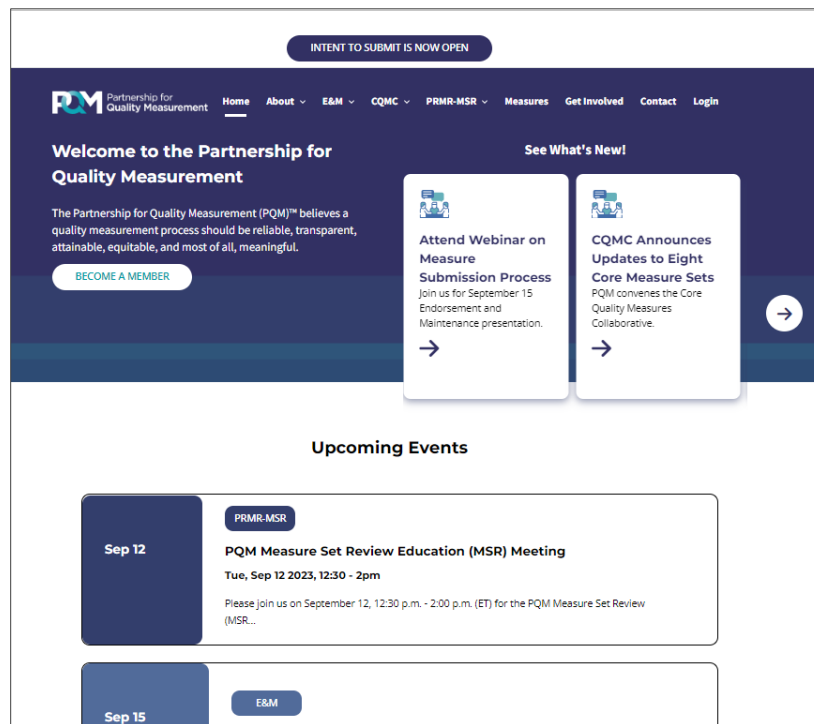


Figure 8: Screenshot of PQM Website www.p4qm.org.

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 recommending measures for pre-rulemaking and/or 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.

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

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.

The 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.

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 Forms

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 provided 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 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.

MEASURE DISCLOSURE OF INTEREST FORM

1. Your Name:

Your Organization Affiliation:

Committee Name:

2. Describe any personal or organizational measure conflicts. If None, check here:

a. Measure Under Review:

MUC ID	Measure Title	Measure developer/steward

1. If you have worked as an employee, collaborator, or consultant of the measure developers/stewards listed OR contributed to the development of the measures listed, in any capacity, in the past 5 years, check here:

b. Competing Measure:

MUC ID	Measure Title	Measure developer/steward

1. If you have worked as an employee, collaborator, or consultant of the measure developers/stewards listed OR contributed to the development of the measures listed, in any capacity, in the past 5 years, check here:

3. If you checked either box under 2a. or 2b., please provide a detailed description of the involvement. (Include MUC ID and measure title and measure developer/ steward name:)

Electronic Certification

By executing this Electronic Certification, I certify I have reviewed the Personal/Organizational Disclosure of Interest Form, and the information provided 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 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 Evaluating PRMR and MSR Assertions

Measure developers and/or measure stewards submitting a Measure under Consideration make certain explicit or implicit assertions about the potential benefits and risks/harms associated with implementation for a designated CMS Medicare Quality program. For PRMR, categories of assertions include 1) meaningfulness, 2) appropriateness of scale, and 3) time to value realization, described in more detail. The task of the advisory and recommendation groups is to assess whether the measure developer and/or measure steward assertions about potential benefits and risks/harms are supported by evidence, and whether the assessment of relative benefits and harms warrant inclusion of the Measure under Consideration in the designated CMS Medicare quality program.

Categories of PRMR Assertions:

- A. **Meaningfulness:** Measure is evaluated and tailored to unique needs of the specific program-target population.

In general, a measure is meaningful if the measure matters - the person/patient or entity would make decisions based on the measure (importance), there are known and effective ways of improving on the measure (scientific acceptability), and any barriers to implementing those ways are known and addressed (feasibility/usability). Meaningfulness is necessary for the measure to yield positive benefit to persons/patients and entities. Ideally the meaningfulness of a measure for the health care system more broadly would be established through the E&M process.⁷ The PRMR groups then only consider assertions of meaningfulness specific or unique to the persons/patients or entities of the designated program.

For example, would the benefit of the measure remain by changes to the specifications tailored to the unique features of the specific target population or entity, increases or decreases in reliability due to the number of persons per entity, the unique aspects of the feasibility trade-off between health benefit to patients and reporting burden to entities, or aspects of validity due to the effectiveness of evidence-based interventions in the context of population-specific characteristics, preferences, values, treatment goals, and material clinical outcomes?

⁷ For measures under consideration not previously endorsed through the E&M process, the PQM staff will provide an assessment of endorsability for consideration by the advisory or recommendation groups. The recommendation group is also free to recommend endorsement as a condition of recommendation.

Based on the holistic evaluation of evidence presented for the proposed intended use, please consider the questions:

Measure Name: Measure Number:	Proposed Intended Use:	
Assessment of Benefit	Considering benefit in terms of:	
	<ul style="list-style-type: none"> • Type • Magnitude • Probability • Duration of effects 	<ul style="list-style-type: none"> • Patient / person perspective • Entity perspective
1. Is there any evidence of benefit?	(yes / no) Please list.	
2. What is the extent of uncertainty for the benefits?	(complete and adequate)	
Assessment of Risk/Harms	Considering risk/harms in terms of:	
	<ul style="list-style-type: none"> • Type • Magnitude • Probability • Duration of effects 	<ul style="list-style-type: none"> • Patient / person perspective • Entity perspective
1. Are the known and probable risks/harms more than minimal?	(yes / no) Please list.	
2. What is the extent of uncertainty for the risks/harms?	(complete and adequate)	
Assessment of Benefit-Risk/Harms		
1. Do the benefits outweigh the risks/harms?	(yes / no) Provide rationale.	
2. Do the benefits outweigh the risks/harms, taking into account additional considerations?	(yes / no) Provide rationale.	
3. Can the risks/harms be mitigated, so the benefits outweigh the risks/harms?	(yes / no) Provide rationale.	

B. Appropriateness of scale: Measure is balanced and scaled to meet program-target population specific goals.

Meaningfulness assesses potential benefits and risks/harms of measure implementation for the program overall, or for the average or typical person/patient or entity. However, those benefits and risks/harms may not be distributed equally across identifiable subpopulations of either persons/patients or entities in a specific program-target population. The appropriateness of scale considers the evidence in support of assertions by the measure developer and/or measure steward about how the benefits of the measure are distributed across subpopulations, and conversely how the risks/harms of the measure are distributed across subpopulations, and how those risks/harms of the measure may be mitigated.

For example, would the benefit of the measure be optimized by targeting implementation to high-risk populations and high priority needs, segmenting based on condition incidence and vulnerability to adverse outcomes, targeting implementation investments in clinical areas that have 1) most opportunity for improvement or 2) have high-cost expenditures for the program, or targeting implementation strategy to persons and entities with established programs and capacity necessary for effective deployment of an evidence-based service delivery model?

Based on the holistic evaluation of evidence presented for the proposed intended use, please consider the questions:

Measure Name: Measure Number:	Proposed Intended Use:	
Assessment of Benefit	Considering benefit in terms of:	
	<ul style="list-style-type: none"> • Type • Magnitude • Probability • Duration of effects 	<ul style="list-style-type: none"> • Patient / person perspective • Entity perspective
1. Is there any evidence of benefit <i>for subpopulations</i> ?	(yes / no) Please list.	
2. What is the extent of uncertainty for the benefits <i>for subpopulations</i> ?	(complete and adequate)	
Assessment of Risk/Harms	Considering risk/harms in terms of:	
	<ul style="list-style-type: none"> • Type • Magnitude • Probability • Duration of effects 	<ul style="list-style-type: none"> • Patient / person perspective • Entity perspective
1. Are the known and probable risks/harms more than minimal <i>for subpopulations</i> ?	(yes / no) Please list.	
2. What is the extent of uncertainty for the risks/harms <i>for subpopulations</i> ?	(complete and adequate)	
Assessment of Benefit-Risk/Harms		
1. Do the benefits outweigh the risks/harms <i>for subpopulations</i> ?	(yes / no) Provide rationale.	
2. Do the benefits outweigh the risks/harms <i>for subpopulations</i> , taking into account additional considerations	(yes / no) Provide rationale.	
3. Can the risks/harms be mitigated <i>for subpopulations</i> , so that benefits outweigh the risks/harms?	(yes / no) Provide rationale.	

C. Time to value realization: Measure has a plan for near- and long-term positive impacts on the targeted program and population as measure matures.

Measures mature over time as implementation in a CMS Medicare quality program often generates the availability of new data, new evidence on ways to improve, or new tools, processes, or people to address barriers to implementing those ways. The time to value realization considers the evidence in support of assertions by the measure developer and/or measure steward about how the benefits of the measure may be realized over time and in what timeframe, or conversely how the risks/harms of the measure may be mitigated over time and in what timeframe. Because these benefits and mitigations will not be realized until the measure is implemented, the Measure Set Review (MSR) process will consider the degree of realization relative to the asserted plan.

For example, would the benefit of the measure be realized over time by equipping persons and entities with tools to access interventions that yield improvement long-term outcomes, enabling more timely prevention and clinical action yielding cost avoidance from downstream hospital admissions and rehabilitation, allowing health care system to optimize existing infrastructure and human capital, adopting a digital specification, driving the equitable distribution and availability of high quality care, increasing access to specialty care or reducing barriers to access for rural persons?

Based on the holistic evaluation of evidence presented for the proposed intended use, please consider the questions:

Measure Name: Measure Number:	Proposed Intended Use:	
Assessment of Benefit	Considering benefit in terms of:	
	<ul style="list-style-type: none"> • Type • Magnitude • Probability • Duration of effects 	<ul style="list-style-type: none"> • Patient / person perspective • Entity perspective
1. Is there any evidence of benefit <i>over time</i> ?	(yes / no) Please list.	
2. What is the extent of uncertainty for the benefits <i>over time</i> ?	(complete and adequate)	
Assessment of Risk/Harms	Considering risk/harms in terms of:	
	<ul style="list-style-type: none"> • Type • Magnitude • Probability • Duration of effects 	<ul style="list-style-type: none"> • Patient / person perspective • Entity perspective
1. Are the known and probable risks/harms more than minimal <i>over time</i> ?	(yes / no) Please list.	

2. What is the extent of uncertainty for the risks/harms <i>over time</i> ?	(complete and adequate)
Assessment of Benefit-Risk/Harms	
1. Do the benefits outweigh the risks/harms <i>over time</i> ?	(yes / no) Provide rationale.
2. Do the benefits outweigh the risks/harms <i>over time</i> , taking into account additional considerations	(yes / no) Provide rationale.
3. Can the risks/harms be mitigated <i>over time</i> , so that benefits outweigh the risks/harms?	(yes / no) Provide rationale.

Based on the assessment, please indicate if the evidence presented for each assertion are 1) complete and adequate, 2) incomplete or inadequate but with plausible path forward, or 3) incomplete or inadequate with no plausible path forward.

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: Measure is evaluated and tailored to unique needs of specific program-target population			
Appropriateness of scale: Measure is balanced and scaled to meet program-target population specific goals			
Time to value realization: Measure has plan for near- and long-term program-target population impact as measure matures			

Source: Adapted from “A Value-Driven Framework for Evaluating Healthcare Innovations,” U.S. Department of Veterans Affairs (Fall 2021). URL: https://www.innovation.va.gov/ecosystem/assets/documents/ExecutiveReport_ValueDrivenFramework.pdf

Do you recommend the Measure Under Consideration for the designated CMS Medicare quality program?

Overall	Recommend	Recommend with conditions (Please specify the conditions)	Do not recommend
Measure under consideration			

MSR Assertions

For MSR, categories of assertions include 1) impact, 2) clinician data streams, and 3) patient journey, described in more detail. The task of the MSR Recommendation Group is to assess whether assertions about potential pros and cons for retaining a measure under review in the program under consideration are supported by evidence, and whether the assessment of relative pros and cons warrant the recommendation for retention or removal.

Categories of MSR assertions:

- A. **Impact:** Core criteria for Measure are evaluated across program, target population, and time.

When measures are initially added to programs, the decision to add the measure was potentially supported by either an endorsement process and/or rulemaking or similar process to review evidence in support of the core E&M criteria. Those criteria demonstrate the meaningfulness necessary for the measure to yield positive benefit. Often that evidence was generated from pilot studies or review of the literature. However, since the initial measure adoption decision, the measure has been implemented in a program, and the implementation experience enables consideration of additional or new information to inform whether the measure should remain in the program.

For example, the additional information may inform whether the measure still aligns with goals and priorities, has continued to demonstrated reliability and validity, retains feasibility of data collection and reporting, and most importantly, the community developed tools, processes, and people to improve measure performance.

- B. **Entity data streams:** Measure set redundancy in data streams is identified and mitigated.

Measures individually may be determined to be feasible to collect and report quality data, and the benefit of such data collection and reporting may exceed the burden. However, a measure set collectively may not align well with the target population, the data source, or the reporting mechanism. Each instance of non-alignment may contribute to additional burden from the perspective of the reporting entity. The intent of this category is to be explicit about those areas of non-alignment, and to consider whether any such associated burden might be mitigated or otherwise addressed.

For example, related measure specifications may use slightly different age ranges, inclusion criteria, or exclusion criteria, use source data from claims, electronic health records, or registries, report using data submission portals, or through electronic health information exchange. Each one of these measure data collection and reporting particulars may increase the potential burden on reporting entities.

C. Patient journey: Measure set is implemented across the patient journey in a manner consistent with the measure set impact model.

The patient or person journey through the health care or social care system might be defined in various ways, including the home-to-home care experience for specific events (home, ambulatory, acute, post-acute, home) or the life-time journey (wellness, diagnosis, acute or chronic illness, advanced illness) or some other care model. Corresponding with these patient journeys are measure set impact models that suggest the optimal what, why, where, when, who, how, how much for the measure response. The intent of this category is to be explicit about those optimal impact considerations from the perspective of the patient or person journey.

For example, some measures might be most impactful at the population level while others may be more clinician knowledge or context dependent.; Some measures might be most impactful at an early stage vs. later stage and some measures might be most impactful on vulnerable patients or persons vs. everyone. The default tends to be measures on everybody, everywhere, all the time, but a more targeted approach might be more optimal for scarce measurement resources.

Based on the holistic evaluation of evidence presented for the measure, please consider the pros and cons:

E&M Criteria	Question	Common Program Removal Criteria	Common Evidence	Pros (the measure should be retained in the program)	Cons (the measure should be removed from the program)
Importance	Align with goals and priorities	Factor 2	Causal link with impact on health outcomes	(e.g., fistula is the preferred mode of vascular access for patients in hemodialysis)	(e.g., recent evidence has suggested a fistula may not be optimal for some patients)
		Factor 1	Performance scores by decile in recent data		
Reliability	Scientifically Sound		Reliability by volume deciles in recent data		
Validity	Provider can influence outcome	Factor 3	Articulated mechanisms to improve performance		
Feasibility	Minimize Burden	Factor 6.	Burden-benefit trade-off		
Usability	Opportunity for Improvement		Articulated tools to improve performance or to receive feedback on performance		
Threats to Validity	Risk-adjustment account for factors outside control?		Risk adjustment conceptual model		
Other		Factor 4			
		Factor 5			

Common Program Removal Criteria:

Factor 1 – Measure performance among the majority of facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made.

Factor 2 - Performance or improvement on a measure does not result in better or the intended patient outcomes.

Factor 3 – A measure no longer aligns with current clinical guidelines or practice.

Factor 4 – A more broadly applicable (across settings, populations, or conditions) measure for the topic or a measure more proximal in time to desired patient outcomes for the particular topic becomes available.

Factor 5 – A measure more strongly associated with desired patient outcomes for the particular topic becomes available.

Based on the assessment, please indicate if the evidence presented for each assertion are 1) complete and adequate, 2) incomplete or inadequate but with plausible path forward, or 3) incomplete or inadequate with no plausible path forward:

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
<i>Impact:</i> Core criteria for Measure are evaluated across program, target population, and time			
<i>Clinician data streams:</i> Measure set redundancy in data streams is identified and mitigated			
<i>Patient journey:</i> Measure set is implemented across the patient journey in a manner consistent with the measure set impact model			

Do you recommend the measure to be retained or removed from the designated CMS quality program:

Overall	Recommend	Do not recommend
Measure under review		

Appendix C. Summary of the Public Comments

The draft Guidebook of Policies and Procedures for PRMR and MSR (hereafter referred to “the Guidebook”) was posted on the PQM website for public comment from June 22, 2023 through July 30, 2023. PQM received a total of 29 comments, 28 submitted through the PQM website and one was submitted through the ServiceNow portal. Of the 29 comments, one was a confirmed duplicate, and another pertained to the E&M Guidebook resulting in a total sample of 27 comments specific to the Guidebook of Policies and Procedures for PRMR and MSR.

Commenters were asked if their comments fell into one or more of the categories: General, Committee structure, Conflict of Interest, Processes, Quorum and voting, and Evaluation Rubric.

All comments received have been posted on the [PQM Website](#).

Comment Themes

A summary of key points and high-level topics emphasized by commenters:

Committee Structure: Committee Representation, Transparency in Committee Selection, Distinctions and Definition of Committee Groups

1. Representation on committees either missing, unclear, or not explicitly stated. Commenters were concerned that key expertise may be missing from committees. These included but were not limited to clinical expertise, quality measurement expertise, CMS program expertise, and general perspective representation.

To address these concerns, we updated the Guidebook by:

- Adding a roster table stating the types of expertise that will be represented on each committee, and
 - Editing some roster categories to be more inclusive and diverse.
2. Transparency in committee selection. Questions arose regarding the transparency in committee selection for the advisory and recommendation groups. These included questions on term length and randomization.

To address these concerns, we have:

- Added language detailing the intent of randomization (to maximize fairness and inclusivity).
 - Added clarifying language about the process by which we will randomize membership to improve transparency.
3. Distinction and Definition of Committee Groups. Commenters expressed the need for more clarification on individual vs. organizational members, eligibility for MSR Recommendation Group appointment, and any group difference or overlap between the Advisory and Recommendations Groups.

To address these concerns, we have

- Updated language to clarify these distinctions.
- Defined the eligibility for MSR Recommendation Group.

Processes: Changes to Comment Periods and Use of Battelle Staff as Facilitators

1. **Changes to Comment Periods.** Multiple commenters expressed the need for clarity or a change in the number of comment periods or timeline of those comment periods. Concerns included needing an additional public comment (e.g., after the recommendation group meetings) for PRMR and public comment periods for MSR would overlap with other high priority tasks.

To address the first concern, we have:

- Added a second PRMR comment period to the process after the recommendation group committee submits their final recommendations to CMS. The intent of this added public comment period is to allow additional feedback to CMS from the public on the proposed recommendations.

Addressing the second concern, we understand overlapping timelines associated with the proposed MSR timeline. Battelle has worked hard to minimize overlap between PRMR, MSR, and Endorsement & Maintenance processes, and in future cycles we will evaluate external timeline conflicts and avoid overlaps where feasible.

Use of Battelle Staff as Facilitators. There were several comments expressing concerns with Battelle staff facilitating the recommendation group meetings to ensure the meeting outcomes are independent and transparent. Battelle staff are trained to facilitate meetings of this caliber and are able to ensure the rigor into the review process is maintained. To address these concerns, each of the recommendation groups will now have two co-chairs who will work with Battelle staff to establish 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.

Consensus: Agreement with increasing consensus to 75%

Commenters tended to agree with **increasing the consensus threshold to 75%**, but some concerns were expressed with this change.

There will be no change to the threshold. Consensus does not mean unanimity.

Quorum: Live Meetings and Voting.

Some commenters expressed **concerns related to off-line voting and informed voting** if a live meeting was missed.

There will be no changes to the process, but we have provided clarity around the quorum threshold for both voting and discussion.

Evaluation Criteria: Additional Guidance

Commenters requested **additional guidance** for PRMR criteria (time to value realization, meaningfulness, appropriateness of scale) and MSR criteria (impact and patient journey).

We have expanded the guidance in Appendix B of the Guidebook to add clarity to the evaluation criteria.

General

We received several more general comments regarding the need for rewording, more detail, formatting, and improved definitions. This version of the Guidebook reflects these suggestions. Several commenters indicated the need for alignment with policies. More specifically, the comments alluded for the proposed policies and procedures to be in alignment with the National Technology Transfer and Advancement Act (NTTAA) of 1995 (631) and the Management and Budget Circular A-119 (631). We appreciate the feedback and note, while these seminal federal policies have laid the groundwork for the voluntary CBE process and provide the general guidance on the CBE attributes, they are not related to the Pre-Rulemaking Measure Review. The PRMR process is not a consensus development process but rather a multi-interested party-led review and recommendation process.

