

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



Table of Contents

			Page
Chang	ges to th	ne Guidebook	1
Chapte	er 1. Pr	e-Rulemaking Measure Review & Measure Set Review	3
1.1	Over	view	3
	1.1.1	Pre-Rulemaking Measure Review	3
	1.1.2	Measure Set Review	3
	1.1.3	PRMR and MSR Scope and Approach	4
	1.1.4	Annual PRMR and MSR Timeline	5
Chapt	er 2. Oı	ganization of Interested Party Committees	7
2.1	Over	view	7
	2.1.1	PRMR Committees	7
2.2	Com	mittee Nomination Process	8
	2.2.1	Committee Member Roster Categories	8
	2.2.2	Federal Liaisons	11
	2.2.3	Time Commitment	11
2.3	PRM	R Committee Structure	12
	2.3.1	Hospital Committee	12
	2.3.2	Clinician Committee	12
	2.3.3	PAC/LTC Committee	13
	2.3.4	Advisory and Recommendation Groups	13
	2.3.5	Appointment to the Advisory and Recommendation Groups and Term Length	15
	2.3.6	Appointment of Subject Matter Experts	16
2.4	MSR	Committee Structure	16
Chapte	er 3. Pf	RMR and MSR Process and Evaluation	17
3.1	Over	view	17
3.2	Appr	oach for Gathering Input	19
3.3	PRM	R Process	19
	Step ²	: MUC List Released	19
	Step 2	2: Preliminary Assessments	19
	Step 3	3: Information Collection	20
	Step 4	l: Information Synthesis	20
	Step 5	5: Advisory Group Discussion Session	21
	Step 6	S: Recommendation Group Meetings	21

	Step 7: Second Public Comment Opportunity	22
3.4	MSR Process	22
	Step 1: Review of Cascade of Meaningful Measures (Cascade) Priorities	23
	Step 2: Information Collection & Synthesis	23
	Step 3: Recommendation Group Pre-meeting Initial Evaluation	24
	Step 4: Recommendation Group Meetings	24
3.5	Measure Evaluation	25
3.6	Timeline	27
Chapte	er 4. Voting Procedures	29
4.1	Overview	29
4.2	Establishing Consensus	29
	4.2.1 PRMR Consensus	29
	4.2.2. PRMR Conditions	30
	4.2.3 MSR Process Consensus	31
4.3	Quorum	31
4.4	Facilitation	31
Chapte	er 5. Public Engagement	32
5.1	Overview	32
5.2	Methods of Engagement	32
5.3	Modes of Communication	33
	5.3.1 PQM Website	33
	5.3.2 Newsletter and Email Alerts	34
Chapte	er 6. Conflict of Interest	35
	What is a COI?	35
	How to Report	35
Appen	dix A. Disclosure of Interest Forms	37
Appen	dix B. Consensus-Based Entity (CBE) Policy on Instrument-based Clinical Quality Measures	41
Appen	dix C. Supplemental Guidance on Evaluating PRMR and MSR Criteria	42

List of Tables	Page
Table 1: Summary of PRMR and MSR scope and approach	5
Table 2: Roster categories and target number of individuals for PRMR and MSR	10
Table 3: Overview of the approach for gathering input	19
Table 4. Anticipated MSR review schedule.	22
Table 5: PRMR criteria and corresponding PIE questions	26
Table 6: Overall recommendation of the measure under consideration for the designat Medicare quality program.	
Table 7: MSR criteria and corresponding PIE form questions Error! Bookmark no	t defined.
Table 8: Overall recommendation of the measure to be retained in the designated CM program Error! Bookmark no	
List of Figures	Page
Figure 1: Overview of PRMR and MSR activities and recent changes	2
Figure 2: Standard timeline of PRMR and MSR activities.	6
Figure 3: Organization of interested party committees.	
Figure 4: PRMR and MSR process workflow	14
Figure 5: Overview of the PRMR activities and their associated timelines	
	18
Figure 6: Overview of the MSR activities and their associated timelines	18 28

Changes to the Guidebook

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 continued use of measures in CMS programs. This Guidebook introduces processes and incorporates changes as suggested by interested parties through a public comment period. This Guidebook is updated annually, and all proposed changes undergo a public comment period.

This updated Guidebook includes several process changes:

- Increased Recommendation Group size: the Recommendation Group size increased from 20 people to 25-30 people. The increased size will help reduce occurrence of "consensus not reached" outcome.
- New Advisory Group meeting: the Advisory Group, with the Recommendation Group co-chairs, will meet prior to measure review meetings to ensure adequate Advisory Group input.
- Updated MSR timeline: the work is moving from late fall to late summer/early fall to reduce burden on MSR members.
- Additional information about the "recommend with conditions" we have clarified this PRMR voting status, including how conditions are identified and agreed upon.
- Clarification on voting procedures for instrument-based measures.

Battelle posts the Guidebook of Policies and Procedures for PRMR and MSR for public comment on the Partnership for Quality Measurement (PQM) website.

Figure 1 summarizes the activities and changes documented in this Guidebook.





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 continued use of measures



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



Community **Voices**

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



What's New

- Larger Recommendation Group size to reduce occurrence of "consensus not reached" voting outcome
- New Advisory Group meeting with Recommendation Group co-chairs prior to measure review meetings to ensure adequate advisory group input
- Updated MSR timeline
- · Additional information about the "recommendation with conditions" PRMR voting status
- Clarification on voting procedures for instrument-based measures

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 PRMR and MSR processes is to solicit interested party input to inform the selection and continued use, respectively, of health care quality and efficiency measures for use in CMS Medicare quality programs. The interested parties include those who are impacted or affected by the use of quality and efficiency measures such as 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 HHS CMS to receive input on measure selection and continued use.

1.1.1 Pre-Rulemaking Measure Review

HHS, per statute,¹ annually publishes (by December 1) a list of measures under consideration (MUC) for future federal rulemaking. The PRMR process supports consensus recommendations regarding the inclusion of MUCs in CMS quality reporting and value-based programs. The PRMR process assesses if a measure is appropriate for use in a specific CMS program and population of Medicare beneficiaries. Interested parties evaluate measures on whether they are meaningful, tailored to unique

Pre-Rulemaking Measure Review (PRMR) is pronounced *Primer*.

program and population needs, balanced and scaled to meet program-specific goals, and demonstrate a clear vision of near- and long-term program impacts.

1.1.2 Measure Set Review

MSR, another process enabled by statute,² 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 review of measures for continued use of measures in programs**.

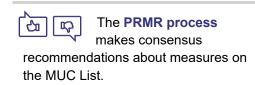
¹ Section 3014 of the <u>Patient Protection and Affordable Care Act</u> of 2010 (ACA) (P.L. 111-148) created section 1890A of the Social Security Act (the Act), which required HHS to establish a federal prerulemaking process for the selection of quality and efficiency measures for use by HHS.

² 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.

The recommendation to review a measure for continued use is based on current information on the measure's properties, performance trends, and whether the measure continues to support the program's needs and priorities.

1.1.3 PRMR and MSR Scope and Approach

Both PRMR and MSR processes are designed to foster collaboration and balance the contributions of various interested parties, resulting in substantiated recommendations for measure selection or continued use to address national health care



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

priorities, fill critical measurement gaps, and increase alignment of measures among programs. The PRMR process assesses the appropriateness of measures included on the MUC List for the intended program and population. By contrast, the MSR process reviews the relative strengths and weaknesses of CMS's current measure portfolio to consider whether those measures continue to meet program and population needs and whether measure removals would reduce redundancy in the portfolio or create a measurement gap.

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 C.

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 the intended CMS program(s) and target population(s)	To build consensus around measure use recommendations through the identification of opportunities to optimize 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	Across the entire CMS measure portfolio, broken into manageable chunks using the Cascade of Meaningful Measures		
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	 Meaningfulness of the concept of interest in the context of use: Measure is evaluated and tailored to unique needs of specific program-target population Appropriateness of scale: Measure portfolio is balanced and scaled to meet target programand population-specific goals; specifically, measure is evaluated in the context of all the measures currently within the program measure portfolio Time to value realization: Measure has plan for near- and long-term positive impacts on the targeted program and population as measure matures 	 Meaningfulness in the context of use: Measure set evaluated across program, target population, and time Patient health care 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 Entity data stream parsimony: Measure set redundancy in data streams is identified and mitigated, specifically by evaluating the burden associated with reporting the measure and considering other related measures 		

1.1.4 Annual PRMR and MSR Timeline

Figure 2 provides the high-level schedule of annual PRMR and MSR activities including:

- Committee member nominations
- MSR process (internal preliminary assessments, public comment periods, committee evaluations, educational meetings, and committee meetings)

• PRMR process (internal preliminary assessments, public comment periods, listening sessions, committee evaluations, educational meetings, and committee meetings)

	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
Nominations	Χ	Х	Х							
MSR Process				Χ	Х	Х				
PRMR Process						Х	Х	Х	Х	Х

Figure 2: Standard timeline of PRMR and MSR activities.

Details about each of these activities are provided in subsequent chapters of this Guidebook.

Chapter 2. Organization of Interested Party Committees

2.1 Overview

Battelle, the consensus-based entity (CBE) that currently holds the CMS National Consensus Endorsement Contract (NCDC), created the Partnership for Quality Measurement (PQM) by bringing together members from across the health care quality landscape who are interested in promoting meaningful quality measurement. Through PQM, Battelle convenes interested parties into committees to participate in PRMR and MSR.

2.1.1 PRMR Committees

There are three PRMR committees grouped by care setting: Hospital, Clinician, and Post-Acute Care/Long-Term Care (PAC/LTC). These committees consist of a diverse membership representing all facets of the health care system. Battelle emphasizes the inclusion of patients/recipients of care, caregivers, patient advocates, and traditionally underrepresented groups to provide input on measures needed for specific care settings, both within and across various CMS programs and patient populations.

PRMR and MSR committees enable participation of up to 180 members in CMS measure selection and continued use.

This committee structure supports the Novel Hybrid Delphi and Nominal Groups (NHDNG), a multi-step hybrid technique used in PRMR, which maximizes engagement of all members and structures facilitation by using standard criteria.

The MSR Recommendation Group does not have a separate nominations process; Battelle annually selects members currently serving on PRMR committees to serve a 1-year term on the MSR Recommendation Group. We use information about the characteristics of measures under review for each MSR cycle to guide membership composition, which consists of 25 to 30 members from across the three PRMR committees (i.e., Hospital, Clinician, and PAC/LTC). Unlike PRMR committees, the MSR cycle has no Advisory Group and only one Recommendation Group, which supports a modified NHDNG approach.

2.2 Committee Nomination Process

Battelle staff annually conduct a review of committee member appointments. This includes an internal assessment of current membership to identify gaps in expertise and determine recruitment needs, a call for public nominations, and targeted outreach. A call for nominations is published on the <u>PQM website</u>, and an announcement is sent to all PQM members. Nominees submit their applications through the PQM website. Both self-nominations and third-party nominations are welcome. Third-party nominations must indicate the organizational or individual nominee has been contacted and is willing to serve. Nominees complete an application form and a Disclosure of Interest (DOI) form (<u>Appendix</u> A). Battelle prioritizes selection of individuals who have participated

All nominees must complete an organization/personal DOI; if appointed, committee members are asked to complete a measure-specific DOI.

in similar panels/committees in the past or who 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. This is balanced with the need to include underrepresented 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. Before finalizing the appointments, Battelle posts a draft roster of nominees on the PQM website to solicit public comment over a 2-week period. Once appointed, all committee members will complete a measure-specific DOI form (Appendix A) at the start of each PRMR or MSR review process.

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 (e.g., primary care providers and specialists, dentists, nurses, pharmacists, physical and occupational therapists, and other health care professionals)
- Facilities/institutions (e.g., accountable care organizations, hospitals or hospital systems, and post-acute/long-term care facilities)
- Clinician associations
- Facility associations
- 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 policymakers)

Committees consist 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 composed of both individual and organizational seats; committee roster categories are listed in Table 2.

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	4	3	3
Clinicians, including primary care providers and specialists	4	3	3
Facility associations	3	2	3
Clinician associations	3	3	3
Facilities/institutions including accountable care organizations, hospitals or hospital systems, and post-acute/long-term care facilities	4	5	3
Purchasers and plans (state, federal, and/or private)	3	2	2
Persons who have experience with rural health (e.g., providers, patients/recipients of care, researchers)	3	2	2
Persons who have experience with health equity (e.g., providers, patients/recipients of care, researchers)	3	2	2
Researchers in health services, alternative payment models, population health	2	2	2
Other interested parties (e.g., EHR vendors and experts in areas such as quality improvement/implementation science, care coordination, patient safety, behavioral health, and national policymakers)	3	3	3
Federal liaisons (non-voting)	TBD, based on specific measures under discussion	TBD, based on specific measures under discussion	TBD, based on specific measures under discussion
Average Total	33	27	27
Range	(30-35)	(25-30)	(25-30)

2.2.2 Federal Liaisons

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 should serve on the committees, based on the specific programs and measures being discussed. Federal liaisons are invited to participate in the Advisory Group and Recommendation Group discussions to help provide context to measures and answer questions.

2.2.3 Time Commitment

Nominees commit to participating in scheduled calls and meetings, providing timely responses to requests for feedback, and being available for ad hoc meetings and conference calls.

For each PRMR cycle (one per year) the time commitment is about 40-60 hours depending on the committee group assignment.

- All committee members are expected to:
 - Answer emails requesting availability or other requests
 - Attend a virtual orientation meeting
 - Conduct assessments of assigned measures under consideration for that PRMR cycle (Note: not all members may be asked to provide written feedback on all measures, but members should be familiar with all measures)
- Recommendation Group members only are expected to:
 - o Review the meeting materials in advance of the all-day review meeting
 - Attend 1- to 2-day virtual measure review meeting
- Advisory Group members only are expected to:
 - Attend a virtual meeting to discuss the measures under consideration with other Advisory Group members and Recommendation Group co-chairs in advance of the Recommendation Group measure review meetings

For each MSR cycle (one per year), the time commitment is about 30-40 hours. MSR committee members are expected to:

- Answer emails regarding availability or other requests
- Attend a virtual orientation meeting
- Conduct assessments of assigned measures for review
- Review materials in advance of the 2-day review meeting
- Attend a 2-day virtual measure review meeting

In the event a member cannot fulfill their commitment and/or is non-responsive to communications for a prolonged period of time, Battelle staff will attempt to contact the member to understand their challenges with fulfilling their commitment and may find a replacement. If the member serves as a representative from a member organization, Battelle staff will contact the organization to find a replacement. If the member serves as an individual representative, Battelle will identify another PRMR committee member to serve.

2.3 PRMR Committee Structure

Battelle convenes three overarching committees to provide input into measure reviews:

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

2.3.1 Hospital Committee

The Hospital Committee provides input on the selection of measures for hospital and hospital-related settings, including inpatient acute, outpatient, cancer, and psychiatric hospitals. The Hospital 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 Program (Hospital IQR)
- Hospital Outpatient Quality Reporting Program (Hospital OQR)
- 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:

- Medicare Part C and D Star Ratings
- Medicare Shared Savings Program (Shared Savings Program)

Merit-based Incentive Payment System (MIPS)

2.3.3 PAC/LTC Committee

The PAC/LTC Committee provides input on the selection of measures for post-acute care and long-term care facilities, including home health agencies, hospices, and skilled nursing facilities. The PAC/LTC Committee provides annual pre-rulemaking input related to:

- 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 PRMR 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 3). MSR does not contain any committees and instead uses a single Recommendation Group, whose members are drawn from all three PRMR committees. Detailed descriptions of the PRMR and MSR processes are included in Sections 3.3 and 3.4.

Advisory (Delphi) Group: Members' participation includes providing written feedback during the PRMR process and attending a virtual meeting with Recommendation Group co-chairs (described further below) to discuss their feedback and generate discussion points and topics for the subsequent Recommendation Group meeting. Their feedback is foundational to the recommendation process as part of the pre-rulemaking process.

Advisory Groups' input is critical to the Recommendation Groups' final consensus recommendations to CMS. Both groups work in tandem to provide meaningful input on the selection of measures.

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

Recommendation Group Co-Chairs: Recommendation Group meetings and the Advisory Group meeting are facilitated by Battelle staff and two co-chairs. Annually, Battelle identifies two members from each committee's Recommendation Group; one co-chair is a patient representative, and the other co-chair represents one of the remaining Recommendation Group roster categories. Each co-chair serves a 1-year term. Their role is to:

 Co-facilitate, along with Battelle staff, the Advisory and Recommendation Group meetings

- Ensure the Recommendation Group discussion is inclusive of Advisory Group feedback and public comments
- Work with Battelle staff to achieve consensus among the Recommendation Group
- 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 (SMEs) as non-voting members of the committee to augment the committee discussions
- Participate as full voting members

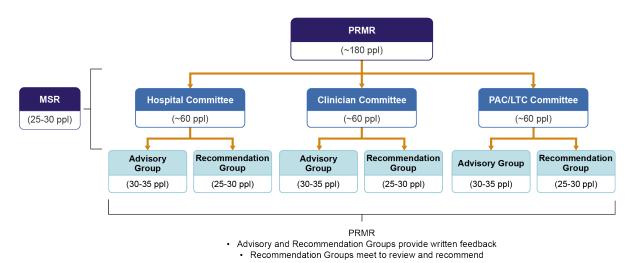


Figure 3: Organization of interested party committees.

To ensure representation across the various populations of interested parties, approximately 60 members are recruited to each of the setting-specific PRMR committees, of which 30 to 35 are

appointed to each Advisory Group. Each PRMR Recommendation Group has 25 to 30 members. The MSR Recommendation Group includes 25 to 30 members drawn from the setting-specific PRMR committees. Battelle develops a roster for each setting-specific PRMR committee based on categories depicted in Table 2. Roster categories have both individual and organizational seats,

Individual vs. Organizational Seats

While most PRMR committee members are individual appointments, certain roster categories are organizational.

Organizations can identify their representatives.

meaning PRMR committees are made up of individuals representing their own interests (individual seats) and individuals representing the interests of an organization (organizational seats). Additionally, there may be instances when two individuals from the same organization may serve on a committee while representing different categories within the same setting-specific committee. For example, within the Hospital Committee, two individuals from the same hospital organization may represent the clinician roster category and the facility roster category, respectively.

2.3.5 Appointment to the Advisory and Recommendation Groups and Term Length

To ensure fairness, Battelle established a process to randomize group assignments. 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

Advisory Group vs. Recommendation Group

Each of Battelle's PRMR committees is 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. This ensures that a larger number of voices contribute to the consensus-building process. MSR is conducted by a single Recommendation Group.

specialists," then three of the seven are randomly assigned to the Recommendation Group. The other four people will serve on the Advisory Group. A committee appointment is for a 3-year term. The process of random assignment is:

- **Step 1:** Within each roster category, identify the pool of eligible nominees.
- **Step 2:** Among participants, allocate by schedule to Advisory or Recommendation Group.

Controlled randomization of Advisory and Recommendation Groups increases transparency.

If the appointed Recommendation Group member is unable to participate, an additional member will be drawn from the roster category pool of eligible nominees. Individuals serve on the Advisory or Recommendation Group for an entire measure review cycle. For the next cycle, assuming their term is still active, another member is randomly selected for the Recommendation Group. All committee members have the opportunity to participate at least

once on the Recommendation Group during their 3-year term.

During the 3-year appointment, committee members will rotate between Advisory and Recommendation Groups. Every member will serve at least 1 year on the Recommendation Group.

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 nominees. An incoming

nominee, if selected for a committee, would serve a full 3-year term. There is no limit on how many times an individual or organization can apply to serve on a committee.

2.3.6 Appointment of Subject Matter Experts

On an as-needed basis, the membership of the Recommendation Group may be supplemented 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 existing members of the group have that expertise. The process of recruitment of these experts is guided by the MUCs under review (for PRMR) and characteristics of the measures under review (for the MSR). 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 Recommendation Group 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 MSR Committee Structure

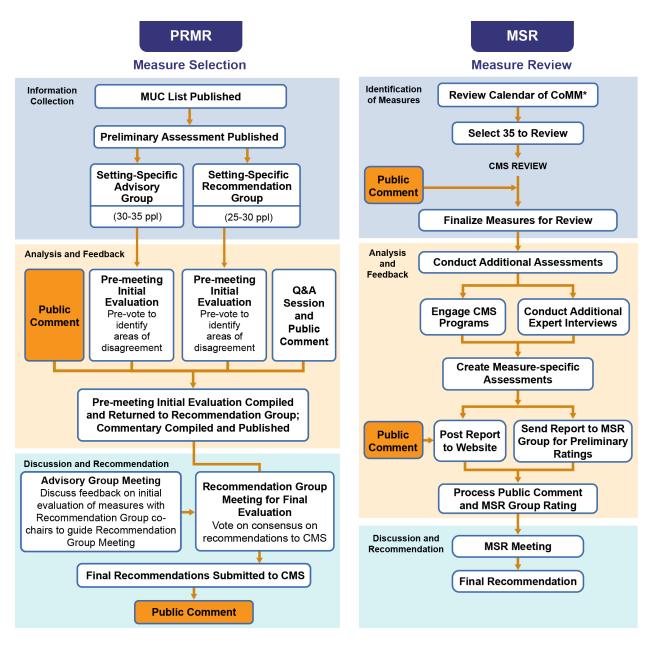
PRMR committee members play a significant role in the MSR process as well. Battelle identifies a select group of PRMR committee members to invite to serve on the MSR Recommendation Group. Battelle considers several factors including the level of engagement as committee members, roster category, and their particular expertise or perspective as related to the specific set of measures under review. MSR Recommendation Group appointment is on an annual basis. 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 includes 25 to 30 members and is inclusive of representatives across the three different settings (Hospital, Clinician, and PAC/LTC) in the PRMR process. Additional information on the MSR schedule is available in Chapter 3.

Chapter 3. PRMR and MSR Process and Evaluation

3.1 Overview

The PRMR and MSR evaluation processes involve 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 to 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 that involves
 qualitative assessment of portfolios of measures across programs and is guided by
 interested parties' input. Figure 4 presents an overview of these processes.



^{*}Cascade: Cascade of Meaningful Measures.

Figure 4: PRMR and MSR process workflow.

3.2 Approach for Gathering Input

For PRMR and MSR, 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	Number of Individuals Format of Input Engaged		PRMR	MSR
General Public	Unlimited	Members of the public may provide written public comment on the PQM website during the posted public comment period.	x	x
General Public	Unlimited, registration recommended	Members of the public may provide verbal public comment during listening sessions attended by Battelle and appropriate CMS staff.	x	
Advisory Group	30-35	The Advisory Group provides feedback on evaluation criteria and merits/challenges of each measure in writing and during discussion session with Recommendation Group facilitators.	X	
Recommendation Group	25-30	The Recommendation Group provides feedback on evaluation criteria and merits/challenges of each measure in writing and meets to vote on measures.	X	X

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.

3.3 PRMR Process

Each PRMR cycle follows the steps outlined below and timeline specified in Section 3.6:

Step 1: MUC List Released

MUC List is made available publicly by December 1 of each calendar year.

Step 2: Preliminary Assessments

In time for the December 1 MUC List release, Battelle staff develop Preliminary Assessments (PAs) of the measures on the MUC List. The PAs include evaluation of each measure's scientific acceptability properties. These assessments involve multiple data sources including the information submitted through the CMS Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT); discussion with measure stewards and developers, as needed; and the PQM Submission Tool and Repository (STAR) database, as needed. The PA evaluates 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.

Step 3: Information Collection

Prior to the Advisory Group and Recommendation Group meetings, the Advisory and Recommendation Groups complete the Pre-Meeting Initial Evaluation (PIE) form and the general public has the opportunity to provide written and oral public comment.

a) PIE: 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 evaluating the assertions of each measure. Both Advisory and Recommendation Group members consider the evidence presented in the PAs and submit initial feedback on the measures via the PIE form.

Both the Advisory and Recommendation Groups submit ratings and explanations of ratings on the measures via the Pre-Meeting Initial Evaluation (PIE) form.

b) Opportunity for written and oral public comment: Battelle issues a 21-day comment period concurrent with publication of the MUC List (on or before December 1 of each year). Prior to the close of the public comment period, Battelle hosts three public listening sessions, one per setting (i.e., hospital, clinician, PAC/LTC), to increase opportunities for comment on MUC List measures. Anyone can sign up for the sessions through the PQM website using an

New Opportunity to Provide
Feedback: The Advisory Group
convenes with Recommendation
Group co-chairs to provide
additional feedback and
develop/raise questions in
preparation for the
Recommendation Group meeting
and vote.

online form and indicate if they wish to give a brief oral statement on one or more measures of their interest. Battelle staff compile the comments received during the public comment period and the listening sessions and make them publicly available on the PQM website no later than 5 days after the close of the public comment period.

Step 4: Information Synthesis

Battelle staff compile and synthesize information collected from the public comment process and from PRMR committee PIE forms to support the Recommendation Group meetings. Compiled comments and PIE results from the Advisory and Recommendation Groups are shared with the Recommendation Group and used to identify areas of non-

consensus to focus on during the Recommendation Group meeting and for Recommendation Group consideration during voting.

Step 5: Advisory Group Discussion Session

Advisory Group discussion session: A week or two prior to the Recommendation Group meetings, members of the Advisory Group convene to discuss their feedback from the PIE forms and help generate discussion questions for the Recommendation Group meeting. The Advisory Group feedback is critical guidance for the Recommendation Group discussion. Recommendation Group co-chairs facilitate the session, and relevant Battelle staff attend. The co-chairs ensure that the Advisory Group perspective is represented throughout the Recommendation Group meetings.

Step 6: Recommendation Group Meetings

Recommendation Group meetings: In mid- to late-January, the Recommendation Group meets to discuss issues/concerns raised during the Advisory Group discussion, public comment period, and via PIE forms. PIE results are shared with the Recommendation Group at least 2 weeks prior to the meeting to assist the Recommendation Group in prioritizing their discussions on areas of non-consensus.

Meeting Procedure: Each setting-specific Recommendation Group meets virtually for 1 or 2 full days (depending upon the number of measures under review) in mid- to late-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 written and oral public comment, PIE results, and programmatic objectives. The co-chairs will provide an overview of Advisory Group feedback they received during the Advisory Group discussion session.

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 opens 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: Recommendation Group members then vote on the discussed measures individually. Instrument-based measures (e.g., Consumer Assessment of Healthcare Providers and Systems [CAHPS]) are also voted on individually (see Appendix B for the CBE policy on instrument-based measures). More detail on the consensus, defining conditions of recommendations, 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 a unique point of view.

Recommendation Groups meet in January of each calendar year to make final consensus recommendations to CMS.

Step 7: Second Public Comment Opportunity

Final recommendations from the Recommendation Group meeting are published on the PQM website on February 1 of each year for a second 15-day public comment period. The intent of this opportunity is to provide additional feedback on the measures under consideration and the final recommendations to CMS. The feedback from the public comment period does not have an impact on the final recommendations.

3.4 MSR Process

Battelle aims to strategically consider all measures used in CMS quality programs for MSR over the course of a 5-year period. To make the MSR process manageable, the portfolio has been divided into three cycles using the <u>Cascade of Meaningful Measures</u> as a guide (see Table 4).

Table 4. Anticipated MSR review schedule.

Year	Cycle	Cycle Description	Cascade of Meaningful Measures Priorities (Number of Measures)
Year 1 – Pilot Year	N/A	To pilot the MSR process, the year 1 cycle focused on measures in the End Stage Renal Disease (ESRD) Quality Improvement Program (QIP).	• N/A (15)
Year 2	Cycle C: Cost- Effectiveness and Efficiency in Health Care Utilization	This group of measures addresses the financial and operational aspects of health care delivery.	Affordability and Efficiency (107)
Year 3	Cycle A: Patient- Centered and Outcome-Focused Care	This group of measures focuses on the individualized needs of patients, emphasizing personalized	 Person-Centered Care (131) Wellness and Prevention (88)

Year	Cycle	Cycle Description	Cascade of Meaningful Measures Priorities (Number of Measures)
		care plans, preventive measures, and chronic disease management.	
Year 4	Cycle A: Patient- Centered and Outcome-Focused Care (Continued)	See above.	 Chronic Conditions (116) Behavioral Health (80)
Year 5	Cycle B: Safety, Quality, and Equity in Health Care Delivery	This group of measures focuses on creating a safe, equitable, and coordinated health care environment.	Safety (132)Seamless Care Coordination (31)Equity (5)

Each MSR cycle follows the steps outlined below:

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

The <u>Cascade of Meaningful Measures (Cascade</u>) 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 priority 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 policymakers 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 priorities 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 MSR measures for a 15-day public comment period. The initial set includes the rationale for measure set selection as well as descriptions for each measure and links to the CMS Measures Inventory Tool to obtain additional measure details (e.g., measure type, specifications). The purpose of the first public comment period is to solicit information on the proposed measure set and rationales for additions or deletions from the list. Comments are compiled, synthesized, and integrated to develop a final set of measures for review for the MSR cycle.

Battelle conducts a PA on the final set of measures that includes analysis of 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. 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 individual measures' purpose. Battelle synthesizes information collected from these various sources to develop measure-specific reports, which are then published on the PQM website for a 30-day public comment period.

Step 3: Recommendation Group Pre-meeting Initial Evaluation

Battelle shares the draft measure-specific reports with the MSR Recommendation Group along with guidance on how to evaluate measures against the measure evaluation criteria using a simple form (PIE). The purpose of this step 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 PIE forms to aid the MSR Recommendation Group meeting. Compiled comments and ratings are then used to identify areas of non-consensus to focus on during the Recommendation Group meeting. A summary of PIE results, along with compiled public comments from Step 2, 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 public comment and PIE results.

Meeting Procedure: The MSR Recommendation Group meets virtually for 1 or 2 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 public comment, PIE results, 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 will call on the Recommendation Group for discussion. CMS staff, Battelle staff, and measure developers will respond to clarifying questions on the PA and the specifications of the measure, as necessary.
- Step 4: Recommendation Group members then will vote on the discussed measures individually. Instrument-based measures (e.g., CAHPS-based measures) are also voted on individually (see <u>Appendix B</u> for the CBE policy on

instrument-based measures). Once the vote for one measure is tabulated, the next measure is discussed and voted on. A simple majority determines the voting outcome for each measure.

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 (based on a simple majority vote) 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 assertions 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 meet 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 C.

When committee members are presented with the PAs, they evaluate—in PIE forms—the measures based on the evidence presented. Committee members do not have to complete a PIE on each measure; to reduce committee burden, Battelle assigns them a subset of the proposed measures. However, members are expected to be familiar with all the measures under review by their committee. 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 C). Committee members must specify and explain if they consulted additional evidence during their evaluation.

Committee members are asked to provide feedback using the questions shown in Table 5 (PRMR) and Table 7 (MSR) and make one of the following determinations regarding the evidence:

- 1. Evidence is complete and adequate: Recommend
- 2. Evidence is either incomplete or inadequate but there is a plausible path forward: Recommend with conditions

Committee Evaluation Guidance

Appendix C includes more detailed information for committee members on how to appropriately consider measures under review.

3. Evidence is either incomplete or inadequate and there is no plausible path forward: Do not recommend

For PRMR, "recommend" means the measure is recommended to CMS to be added to a Medicare quality program (Table 6). In MSR, "recommend" means the measure meets all criteria and is recommended to be retained in the current CMS program (Table 8).

Table 5: PRMR criteria and corresponding PIE questions.

Criteria	PIE Questions
Meaningfulness: Concept of Interest	
Importance: The measure focus is associated with a material outcome for persons and entities	Based on your experience and review of the measure, please discuss if this measure will meet these criteria when implemented in the program population?
Conformance: Measure components and specifications are designed to align with the intent of the measure focus and target population	
Feasibility: The tools, processes, and people necessary to implement and report on the measure are reasonably available	
Meaningfulness: Context of Use	
Importance: The measure's use in the selected quality program will generate benefits that exceed the costs	Based on your experience and review of the measure, please discuss if this measure will meet these criteria when implemented in the program population?
Validity & Reliability: There are known and effective ways that the person or entity should use to improve the measure focus (Validity) and most of the variation in the measure performance is attributable to variation in the aforementioned ways (Reliability) Usability: Any barriers or facilitators to whether the person or entity could use the aforementioned ways are known and addressed	

Criteria	PIE Questions
Appropriateness of Scale	
Appropriateness of Scale: The measure is balanced and scaled to meet program-target population specific goals	If implemented in the program, would all program target populations receive the same net benefit? Would there be identifiable populations or measured entities that did not receive the benefit of this measure equally?
Time to Value Realization	
Time to Value Realization: There are near- and long-term positive impacts on the targeted program and population as the measure matures	If implemented in the program, would the net benefit change (increase or decrease) over time?

Table 6: Overall recommendation for the designated CMS Medicare quality program.

	Recommend	Do not recommend
MSR Measure		

3.6 Timeline

PRMR and MSR both involve 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. As such, the MSR timeline is subject to change in future cycles. Figure 5 and Figure 6 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	Х	Х	Х						
PRMR committees provide written feedback (PIE)	Х	Х	Х						
CMS and Battelle host listening sessions to facilitate Q&A and public comment		Х							
Battelle synthesizes feedback from public comment and PIE			Х	Х	Х				
Advisory Group meetings					Х				
Recommendation Group meetings						Х	Х		
Battelle publishes PRMR recommendations spreadsheet								X	

Figure 5: 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 and consults committee members to identify measures for MSR	X	X	Х	X				
Public comments on measures initially identified for MSR review; Battelle and CMS finalize list of measures				X	X			
Battelle conducts measure evaluation (specific outreach with CMS program/measure leads, internal analyses, ad hoc expert interviews)				X	X			
Battelle develops PAs					Х	Х		
Public comment on PAs						Х	Х	
Measure Set Review: Recommendation Group meeting							Х	Х
Battelle submits final recommendations on MSR to CMS								Х

Figure 6: 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 structures meeting facilitation by using standard criteria and practices. The approach allows committees to maximize the value of the time spent by focusing discussion on aspects of measures where there is disagreement. Both the Advisory and Recommendation Groups provide feedback via the PIE forms. Only the Recommendation Group casts final votes during the virtual measure review meeting to submit consensus recommendations to CMS.

4.2 Establishing Consensus

4.2.1 PRMR Consensus

For the PRMR process, 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 interrater 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. If members do not achieve a 75% or greater agreement, then consensus is not reached. Table 9 describes the consensus achievement process for final recommendations.

Table 7: 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)
		Greater than 25% and less than 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. This approach also encourages meaningful, inclusive discussions to establish more convincing consensus decisions. In addition, committees use iterative ratings as described in Sections 3.3 and 3.4 to support the consensus process and to yield the final recommendation.

4.2.2. PRMR Conditions

PRMR Recommendation Group members may identify certain conditions that, if met, would lead them to a vote to fully recommend the measure. Conditions include improvements that could be made to the measure in the short term (i.e., in the current CMS rulemaking cycle) or on a longer timeline. Short-term conditions may include things such as stratification in reporting, obtaining consensus-based entity endorsement, or performing additional testing to demonstrate measure meaningfulness. Longer-term conditions might include re-specification of the measure focus or target population or the addition or removal of factors in the measure's risk adjustment model. Recommendation Group members do not need to come to agreement on the conditions that would accompany a recommendation status. Rather, each committee member who submits a "recommend with conditions" vote is asked to supply, orally or in writing, the relevant condition(s) they believe should precede the measure's implementation in a CMS program. Battelle staff document the identified conditions in the PRMR Recommendations Report for CMS's consideration. In situations where a measure is being considered for more than one program, Battelle facilitators will call the Recommendation Group's attention to any and all previously noted conditions for their consideration and discussion.

4.2.3 MSR Process Consensus

Unlike the PRMR process, MSR requires a simple majority, greater than 50%, to arrive at a voting outcome (i.e., recommend or do not recommend the measure to be retained). The higher consensus standard for PRMR is applied because decisions to include measures in quality programs have the potential to add burden to persons and entities. This is not the case for MSR.

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"). Both PRMR and MSR follow the same quorum quidelines.

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 less than 60% of members are in attendance, then the Recommendation Group will not discuss the measures and a back-up meeting will be held. Battelle will conduct 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 voting-eligible participants until a voting quorum is reached. When possible, any absent voting-eligible participants will be encouraged to review the recording of the relevant Recommendation Group discussion, when possible, prior to rendering a vote. If quorum is not reached, recommendation of "no consensus" is submitted to 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, keep discussions on track, prevent discussions from being dominated by a small number of participants, and ensure decisions are reached.

Chapter 5. Public Engagement

5.1 Overview

Public engagement activities play a crucial role in ensuring transparent PRMR and MSR processes. Battelle welcomes comments from all interested parties and makes a concerted effort to engage communities with a wide range of diverse backgrounds. To promote accessibility, all public communication complies with <u>Section 508</u>. 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 and during public meetings. Members of the public may also nominate committee members (Section 2.2).

- Public comment process: Members of the public have several opportunities to provide input on measures undergoing PRMR and MSR processes. Both PRMR and MSR have two opportunities each for written public comment where members of the public can submit comments through the <u>PQM website</u>. These steps for public engagement into both the PRMR and MSR processes are critical to ensuring rigor, transparency, and increased engagement.
 - a. PRMR: The first PRMR public comment period occurs when CMS releases the MUC List. The public then has 21 days to provide feedback on the measures. In addition to written public comment for PRMR, Battelle holds three setting-specific listening sessions in December of each year; during these listening sessions, the community has an opportunity to provide verbal feedback to CMS on the MUC List. Following the measure review meetings, there is a second public comment period for 15 days during which members of the public can provide feedback on the committee recommendations to CMS.
 - b. MSR: The first MSR public comment period occurs at the beginning of the cycle, during which members of the public have 15 days to comment on the selected measures for review. The second MSR public comment opportunity occurs prior to the MSR Recommendation Group review meeting. Battelle posts its measure analyses to the website for a 30-day public comment.
- 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, is available to the public on 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 2.2 for details.

5.3 Modes of Communication

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

5.3.1 PQM Website

The <u>PQM website</u> hosts all information relevant to upcoming opportunities for both public and PQM member engagement and serves as the platform for public comment. The PQM website (Figure 7) 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 <u>pgmsupport@battelle.org</u>.

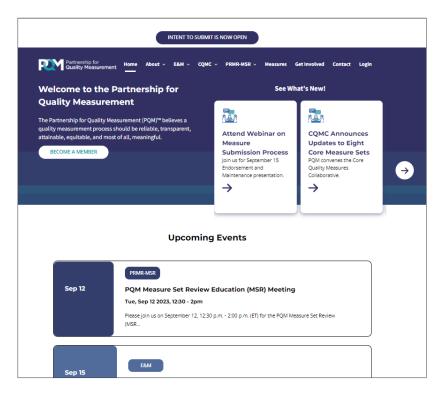


Figure 7: Screenshot of PQM website www.p4gm.org.

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 and a calendar of events, the PQM website announces public comment periods to interested parties. These items are specific to the 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

Battelle shares updates on calls for nominations, public comment periods, committee meetings, meeting materials, and all status updates via newsletter and email alerts. Battelle uses Microsoft Outlook for all committee communications to increase the deliverability of the messages. 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") to all committee members to ensure that committees perform functions in a manner free from bias and undue influence.

What is a COI?

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

How to Report

To complete the COI analysis, each

organizational seat) Disclosure of Interest (DOI) form (<u>Appendix A</u>) 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 within each cycle ahead of measure discussions. 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. All committee members have an ongoing duty to monitor their own

COI issues and those of fellow committee members and raise or disclose any issues either in a

committee member will be required to complete an initial personal and organizational (if

Measure-Specific COI Examples

- 1) A member has directly and substantially contributed to the development of a measure being considered for selection, continued use, or removal. *Example: Serving on a technical expert panel.*
- 2) The member or their spouse, domestic partner, or child could receive a direct financial benefit from a measure being recommended for selection, continued use, or removal. Example. A spouse holds a patent required for a Measure Under Consideration
- 3) 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, continued use, or removal process.
- 4) The member is currently employed by the measure developer or has created a related or competing measures in the topic area.

committee meeting, to the committee chair, or to the Battelle program team.

Additionally, committee members must verbally disclose relevant interests at a public committee meeting, usually at a committee's first public meeting. Following verbal disclosure by committee members, Battelle program staff will allow other committee members to ask questions regarding those disclosures.

Appendix A. Public Comments on the Guidebook

PQM received two public comments on the draft Guidebook via the PQM website during the public comment period of June 4-24, 2024.

Verbatim Comment 1

Health Services Advisory Group

Dear Battelle Team,

On behalf of Health Services Advisory Group, Inc. (HSAG), we appreciate the opportunity to review and comment on the Working Draft Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review (PRMR) and Measure Set Review (MSR) 2024. We are supportive of Battelle's efforts to refine the process and respectfully submit the following comments for consideration:

- Consider a requirement for voting members to listen to the meeting recording prior to casting a vote, in cases when you must reach out to voting members to achieve 80% quorum. The value of the process is hearing the rich dialog in the groups to come to consensus.
- We appreciate the increase in recommendation group size to lessen the occurrence of an outcome of "consensus not reached." We recommend consideration of a mitigation strategy when the same measure receives a "recommend" for one program and a "recommend with conditions" for another program, when the conditions presented by the panel would be applicable across programs.
- We encourage Battelle to align the Categories of PRMR Assertions (e.g., meaningfulness, time to value realization) with required MERIT data submission fields if measure stewards are expected to provide information in the MERIT submission that informs these evaluation criteria.

Thank you for the opportunity to comment.

Response

To address these concerns, in cases where we must reach out to voting-eligible members to achieve 80% quorum, we have added text indicating that voting members should listen to the Recommendation Group recording prior to rendering a vote, when possible (see section 4.3). We have also added language to ensure that conditions mentioned in the discussion for one program are brought forward for the Recommendation Group's consideration when considering the same measure for a different program (see section 4.2.2). We appreciate the desire to align the PRMR Assertions with MERIT data submission fields, though we note that this alignment will require conversations involving multiple contractors across CMS contracts and will be considered as a longer-term goal.

Verbatim Comment 2

Rolanda Murphy

I think the guidebook is well put together as a format for national consensus development and strategic planning for health care quality measurements. I look forward in working with all the groups to arrive at the best solutions to achieve Quality Healthcare for Medicare recipients.

Response

Thank you for taking the time to review and comment on the Guidebook. We very much appreciate your engagement in our work.

Appendix B. Disclosure of Interest Forms

PERSONAL/ORGANIZATIONAL DISCLOSURE OF INTEREST FORM

1.	Your Name:		
	Your Organization Affiliation:		
	Committee Name:		
relation	be any personal or organizational relationships subject to disclosure (e.g., disclosures may include ships with employees of organizations developing or stewarding the measure, stock options in nies 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: \Box		
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:	me: 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 Nar	me:		
2. Describe any personal or organizational measure conflicts. If none, check here: □				
	a. Measure Under Review:			
	MUC ID	Measure Title	Measure Developer/Steward	
	WOOTD	Wedsure Title	Weasure Developer/oteward	
	 i. 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	
	 i. If you have worked as an employee, collaborator, or consultant of the medevelopers/stewards listed OR contributed to the development of the medevelopers, 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:	Signat	ure:	
	Date:			
an	and all other persons and organizations must be free of any conflicts of interest for this effort. If at			

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 C. Consensus-Based Entity (CBE) Policy on Instrument-based Clinical Quality Measures

Overview

Instrument-based clinical quality measures are measures that are derived from instruments or surveys, such as various versions of the Consumer Assessment of Healthcare Providers and Systems (CAHPS), the Hospice Outcomes and Patient Evaluation (HOPE), or End-Stage Renal Disease (ESRD) Patient Life Goals Survey (PaLS).

Policy

The following is the policy of the CBE with respect to instrument-based clinical quality measures:

- The CBE does not review or endorse instruments or surveys. Rather, the CBE reviews and endorses clinical quality measures derived from instruments or surveys.
- Clinical quality measures derived from instruments or surveys must be specified and tested at the accountable entity level (e.g., clinician or facility).
- There are no differences in the requirements or criteria for endorsement & maintenance between instrument-based clinical quality measures and other clinical quality measures. Specifically, all measures are evaluated based on data element-level (i.e., person- or encounter-level) reliability and validity, and accountability entity-level reliability and validity.
- For data element-level reliability and validity, measure developers/stewards may cite existing literature to substantiate those properties.
- Measures developers/stewards are also encouraged to attest that the instrument or survey was developed using a best practice protocol (e.g., Holmbeck, 2009).
- Each clinical quality measure derived from an instrument or survey is reviewed and endorsed separately.
- Measure developers/stewards are encouraged, where appropriate, to combine individual instrument or survey items into a person/respondent-level "composite," which may then be aggregated to the accountable entity-level. Such a measure would be reviewed and endorsed as a single measure.
- CBE staff are available for technical assistance to measure developers/stewards in the application of this policy.

References

Holmbeck GN, Devine KA. Editorial: an author's checklist for measure development and validation manuscripts. J Pediatr Psychol. 2009 Aug;34(7):691-6. doi: 10.1093/jpepsy/jsp046. Epub 2009 May 31. PMID: 19487232; PMCID: PMC2735062. https://pubmed.ncbi.nlm.nih.gov/19487232/

Appendix D. Supplemental Guidance on Evaluating PRMR and MSR Criteria

Measure developers and/or measure stewards-by submitting a Measure Under Consideration-make certain explicit or implicit assertions about the potential benefits and risks/harms associated with measure implementation for a designated CMS Medicare quality program, described in more detail in subsequent sections of this appendix. The task of the Advisory and Recommendation Groups is to test these assertions by evaluating whether they are supported by evidence and argument and whether the assessment of relative benefits and harms warrants inclusion of the measure in the designated CMS Medicare quality program. The criteria for PRMR and MSR are designed to evaluate these assertions.

Categories of PRMR Assertions

For PRMR, categories of assertions include A) meaningfulness (in terms of the measure's concept of interest and context of use), B) appropriateness of scale, and C) time to value realization.

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

Meaningfulness is necessary for the measure to yield net 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.³ The PRMR groups then only consider assertions of meaningfulness specific or unique to the persons/patients or entities of the designated quality program. Meaningfulness can be considered in terms of the measure's concept of interest (i.e., what the measure is about) and in the measure's context of use (i.e., the CMS program or care setting where the measure will be used).

Concept of Interest:

When considering meaningfulness of the concept of interest, committees should evaluate whether the measure provides:

- Evidence that the measure focus is associated with a material outcome for persons and entities (Importance)
- Measure components and specifications that are designed to align with the intent of the measure focus and target population (Conformance)

³ For measures under consideration not previously endorsed through the E&M process, the PQM staff will provide an assessment of readiness for endorsement for consideration by the Advisory or Recommendation Groups. The Recommendation Group is also free to include endorsement as a condition of recommendation during voting.

• Demonstration that the tools, process, and people necessary to implement and report on the measure are reasonably available (Feasibility)

Context of Use:

When considering meaningfulness in the context of use, committees should evaluate whether the measure provides:

- A rationale for why the measure's use in the selected quality program will generate benefits that exceed the costs (Importance)
- Demonstration through data or logic that there are known and effective ways that the
 person or entity should use to improve the measure focus (Validity)
- Demonstration through data that most of the variation in the measure performance is attributable to variation in the aforementioned ways (Reliability)
- Demonstration that any barriers or facilitators to whether the person or entity could use those ways are known and addressed (Usability)
- B. Appropriateness of scale: Measure is balanced and scaled to meet program-target population specific goals.

Meaningfulness asserts the potential net benefits of measure implementation for the program overall or for the average or typical person/patient or entity. However, benefits and risks/harms conferred by the measure may not be distributed equally across identifiable subpopulations of persons/patients or entities within a specific program-target population. Evaluation of the appropriateness of scale assertion considers the evidence about the distribution of benefits and of risks/harms of the measure distributed across subpopulations and how risks/harms of the measure may be mitigated.

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 addresses changes in the benefits or harms that may come from measuring something over time. Committees can evaluate the time to value realization by considering how the harms and benefits change over time, ways the benefits of the measure might be prolonged, and how potential harms could be prevented.

Categories of MSR assertions

For MSR, categories of assertions include A) meaningfulness in the context of use, B) clinician data stream parsimony, and C) relevance to the patient journey. 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 warrants the recommendation for continued use or removal.

A. Meaningfulness: context of use

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.

When evaluating meaningfulness in the context of use, committees should consider if the measure provides:

- Demonstration through data that the measure's use in the selected quality program generates benefits that exceed the costs (Importance)
- Demonstration through data or logic that there are known and effective ways that the
 person or entity should use to improve the measure focus (Validity)
- Demonstration through data that most of the variation in the measure performance is attributable to variation in the aforementioned ways (Reliability)
- Demonstration that any barriers or facilitators to whether the person or entity could use those ways are known and addressed (Usability)
 - B. Entity data stream parsimony: 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; or report using data submission portals or through electronic health information exchange. Each one of these data collection and reporting particulars may increase the potential burden on reporting entities.

When evaluating entity data stream parsimony, committee members should evaluate whether:

- The clinical data flow required for the measure promotes non-burdensome data collection and reporting
 - C. Patient health care journey: Measure set is implemented across the patient health care 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 lifetime 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, and 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.

When evaluating the patient journey, committee members should evaluate whether:

• The measure addresses the appropriate aspects of care to align with the patient health care journey.

