Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS-10849, OMB 0938-1452); Use: Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act ("the Act"). The Act establishes the Negotiation Program to negotiate maximum fair prices ("MFPs"), defined at 1191(c)(3) of the Act, for certain high expenditure, single source selected drugs covered under Medicare Part B and Part D. For the third cycle of the Negotiation Program, the Secretary of Health and Human Services (the "Secretary") will select up to 15 high expenditure, single source drugs payable under Part B and/or covered under Part D for negotiation. In accordance with section 1194(f)(4) of the Act, CMS will also renegotiate MFPs for drugs selected for renegotiation, if any, for initial price applicability year

Negotiation Data Elements: The statute requires that CMS consider certain data from Primary Manufacturers as part of the negotiation process. To the extent that more than one entity meets the statutory definition of manufacturer (specified in section 1193(a)(1) of the Act) for a selected drug for purposes of initial price applicability year 2028, CMS will designate the entity that holds the New Drug Application(s) (NDA(s))/Biologics License Application(s) (BLA(s)) for the selected drug to be "the manufacturer" of the selected drug (hereinafter the "Primary Manufacturer"). The Primary Manufacturer's data submissions include the non-Federal average manufacturer price and related data for selected drugs for the purpose of establishing a ceiling price, as outlined in section 1193(a)(4)(A) of the Act, and information that the Secretary requires, pertaining to the negotiation factors outlined in section 1194(e)(1) of the Act, for the purpose of formulating offers and counteroffers pursuant to section 1193(a)(4)(B) of the Act. Some of these data are held by the Primary Manufacturer and are not currently available to CMS. Data described in sections 1194(e)(1) and 1193(a)(4) of the Act must be submitted by the Primary Manufacturer.

Section 1194(e)(2) of the Act requires CMS to consider certain data on selected drugs and their alternative treatments. Because the statute does not

specify where these data come from, CMS will allow for optional submission from Primary Manufacturers and the public for drugs selected for negotiation or renegotiation. CMS will additionally review existing literature, conduct internal analyses, and consult subject matter and clinical experts on the factors listed in section 1194(e)(2) of the Act. Manufacturers may optionally submit this information as part of their Negotiation Data Elements Information Collection Request Form. The public may also optionally submit evidence about the selected drugs and their alternative treatments.

Drug Price Negotiation and Renegotiation Process: Any MFPs that are negotiated or renegotiated for these selected drugs will apply beginning in initial price applicability year 2028. For initial price applicability year 2028, the negotiation and renegotiation period begins on the earlier of the date that the Primary Manufacturer enters into a Medicare Drug Price Negotiation Program Agreement or February 28, 2026.

Section 1194(b)(2)(C) of the Act provides that if the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer may submit an optional written counteroffer no later than 30 days after the date of receipt of CMS' written initial offer. If the Primary Manufacturer chooses to develop and submit a written counteroffer to CMS' written initial offer during the drug price negotiation or renegotiation process for initial price applicability year 2028, the Primary Manufacturer must submit the Counteroffer Form. Form Number: CMS-10849 (OMB control number: 0938-1452); Frequency: Once; Affected Public: Private sector, Business or other for-profit; Number of Respondents: 405; Number of Responses: 405; Total Annual Hours: 51,940. (For questions regarding this collection, contact Elisabeth Daniel at 667-290-8793.)

#### William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–11980 Filed 6–26–25; 8:45 am]

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3467-N]

Secretarial Comments on the CBE's (Battelle Memorial Institute) 2024 Activities: Report to Congress and the Secretary of the Department of Health and Human Services

**AGENCY:** Office of the Secretary of Health and Human Services, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice acknowledges the Secretary of the Department of Health and Human Services' (the Secretary's) receipt and review of Battelle Memorial Institute's, the consensus-based entity (CBE) under a contract with the Secretary, 2024 Annual Activities Report to Congress, as mandated by section 1890(b)(5) of the Social Security Act (the Act). The Secretary has reviewed CBE's 2024 Annual Report and is publishing the report in the Federal Register together with the Secretary's comments on the report not later than 6 months after receiving the report in accordance with section 1890(b)(5)(B) of the Act. This notice fulfills the statutory requirements. Although the Act requires the Secretary to review and publish the report, this statutory obligation does not constitute endorsement by the Secretary of the CBE's annual report and its specific recommendations.

FOR FURTHER INFORMATION CONTACT: Charlayne Van, (410) 786–8659.

SUPPLEMENTARY INFORMATION:

#### I. Background

The United States Department of Health and Human Services (HHS) has long recognized that a high functioning health care system that provides higher quality care requires accurate, valid, and reliable measurement of quality and efficiency. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275) added section 1890 of the Social Security Act (the Act), which requires the Secretary of HHS (the Secretary) to contract with a consensus-based entity (CBE) to perform multiple duties to help improve performance measurement. Section 3014 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111-148) expanded the duties of the CBE to help in the identification of gaps in available measures and to improve the selection of measures used in health care

programs in Section 1890(b) of the Act. The below comments are regarding the 2024 activities conducted by Battelle as the CBE during that time.

Section 1890(b) of the Act requires the

following:

Priority Setting Process: Formulation of a National Strategy and Priorities for Health Care Performance Measurement. The CBE must synthesize evidence and convene key stakeholders to make recommendations on an integrated national strategy and priorities for health care performance measurement in all applicable settings. In doing so, pursuant to section 1890(b)(1)(A) of the Act, the CBE must give priority to measures that: (1) address the health care provided to patients with prevalent, high-cost chronic diseases; (2) have the greatest potential for improving quality, efficiency, and patient-centered health care; and (3) may be implemented rapidly due to existing evidence, standards of care, or other reasons. Additionally, pursuant to section 1890(b)(1)(B) of the Act, the CBE must take into account measures that: (1) may assist consumers and patients in making informed health care decisions; (2) address health disparities across groups and areas; and (3) address the continuum of care furnished by multiple providers or practitioners across multiple settings.

Endorsement of Measures. Under section 1890(b)(2)(A) through (B) of the Act, the CBE must provide for the endorsement of standardized health care performance measures. This process must consider whether measures are evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, responsive to variations in patient characteristics such as health status, language capabilities, race or ethnicity, and income level and are consistent across types of health care providers, including hospitals and physicians.

Maintenance of CBE Endorsed Measures. The CBE is required to establish and implement a process to ensure that endorsed measures are updated (or retired if obsolete) as new

evidence is developed.

Removal of Measures. Section 102(c) of Division CC of the Consolidated Appropriations Act, 2021 amended section 1890(b) of the Act to permit the CBE to provide input to the Secretary on measures that may be considered for removal.

Convening Multi-Stakeholder Groups. The CBE must convene multistakeholder groups to provide input on: (1) the selection of certain categories of quality and efficiency

measures, from among such measures that have been endorsed by the entity and from among such measures that have not been considered for endorsement by such entity but are used or proposed to be used by the Secretary for the collection or reporting of quality and efficiency measures; and (2) national priorities for improvement in population health and in the delivery of health care services for consideration under the national strategy. The CBE provides input on measures for use in certain Medicare programs, for use in programs that report performance information to the public, and for use in health care programs that are not included under the Act. The multistakeholder groups provide input on quality and efficiency measures for various federal health care quality reporting and quality improvement programs including those that address certain Medicare services provided through hospices, ambulatory surgical centers, hospital inpatient and outpatient facilities, physician offices, cancer hospitals, end stage renal disease (ESRD) facilities, inpatient rehabilitation facilities, long-term care hospitals, psychiatric hospitals, and home health care programs.

Transmission of Multi-Stakeholder Input. Not later than February 1 of each year, the CBE must transmit to the Secretary the input of multi-stakeholder groups. Not later than March 1 of each year, the CBE is required to submit to the Congress and the Secretary an annual report. The report is to describe:

- The implementation of quality and efficiency measurement initiatives and the coordination of such initiatives with quality and efficiency initiatives implemented by other payers;
- Recommendations on an integrated national strategy and priorities for health care performance measurement;
- Performance of the CBE's duties required under its contract with the Secretary;
- Gaps in endorsed quality and efficiency measures, including measures that are within priority areas identified by the Secretary under the national strategy established under section 399HH of the Public Health Service Act (National Quality Strategy), and where quality and efficiency measures are unavailable or inadequate to identify or address such gaps;
- Areas in which evidence is insufficient to support endorsement of quality and efficiency measures in priority areas identified by the Secretary under the National Quality Strategy, and where targeted research may address such gaps; and

• The convening of multi-stakeholder groups to provide input on: (1) the selection of quality and efficiency measures from among such measures that have been endorsed by the CBE and such measures that have not been considered for endorsement by the CBE but are used or proposed to be used by the Secretary for the collection or reporting of quality and efficiency measures; and (2) national priorities for improvement in population health and the delivery of health care services for consideration under the National Quality Strategy.

Section 50206(c)(1) of the Bipartisan Budget Act of 2018 (Pub. L. 115-123) amended section 1890(b)(5)(A) of the Act to require the CBE's annual report to Congress to include the following: (1) an itemization of financial information for the previous fiscal year ending September 30th, including annual revenues of the entity, annual expenses of the entity, and a breakdown of the amount awarded per contracted task order and the specific projects funded in each task order assigned to the entity; and (2) any updates or modifications to internal policies and procedures of the entity as they relate to the duties of the CBE including specifically identifying any modifications to the disclosure of interests and conflicts of interests for committees, work groups, task forces, and advisory panels of the entity, and information on external stakeholder participation in the duties of the entity.

The CBE must also annually provide a report to Congress and the Secretary under section 1890(b)(5)(A) of the Act. Section 1890(b)(5)(B) of the Act provides that no later than 6 months after receiving the annual report, the Secretary shall review such report; and publish such report in the Federal Register, together with any comments of the Secretary on such report. Although the Act requires the Secretary to review and publish the report, this statutory obligation does not constitute endorsement by the Secretary of the CBE's annual report and its specific recommendations.

This **Federal Register** notice satisfies the requirement to Secretarial review and publication of the CBE's annual report under section 1890(b)(5)(B) of the Act. The CBE submitted a report on its 2024 activities to Congress and the Secretary on February 24, 2025. The Secretary's Comments on this report are presented in section II of this notice, and the CBE's 2024 Activities Report to Congress and the Secretary is provided, as submitted to HHS, in the addendum to this **Federal Register** notice in section IV.

#### II. Secretarial Comments on the CBE's (Battelle Memorial Institute) 2024 Activities: Report to Congress and the Secretary of the Department of Health and Human Services

As part of its core mission, HHS seeks to stabilize and improve the quality of health care throughout the country. In response to recent public health crises and to prudently prepare for imminent threats in the future, it is clear that the Department of Health and Human Services (HHS) must continue to focus on advancing better health care for all Americans, strengthening public trust, and building meaningful engagement and learning across the health care system. By embedding the cross-cutting principles 1 of advancing better health care for all Americans, public trust and collaboration into its diverse programs and initiatives, HHS is working to improve the health and well-being of individuals and families.

HHS appreciates the efforts that the CBE has made to support our mutual commitment to promoting a resilient, high value, and safe health care system for all Americans. In 2024, HHS supported the work conducted by the CBE to establish a measure review process that is reliable, transparent, attainable, objective and meaningful. This aligns with both Battelle and HHS' commitment to engaging all populations in health care quality improvement. As the CBE in 2024, Battelle continued to use rigorous standards to review measures for quality measure endorsement and maintain highly reliable and scientifically sound measures across priority health care topic areas.

In 2024, the CBE continued its focus on four key initiatives: Endorsement & Maintenance (E&M) of clinical quality measures, Pre-Rulemaking Measure Review (PRMR), Measure Set Review (MSR) and Core Quality Measures Collaborative (CQMC).

During 2024, Battelle reviewed all measures that were submitted for endorsement consideration for the Fall 2023 and Spring 2024 E&M cycles. Battelle enhanced its focus on advancing measurement science, ensuring transparency and increasing the number of perspectives engaged in the process. This led to greater involvement from patients, advocacy groups, and clinicians, fostering a shared sense of ownership and commitment to quality improvement.

Measures submitted for endorsement addressed critical areas like patient

safety, clinical effectiveness, health access, and cost reduction. The E&M committee identified gaps in quality measurement and provided feedback on how the process could further evolve. In addition to committee feedback, Battelle also identified the need for better guidance in developing measure logic models, quantifying burden and explaining the value of a measure on the system. As the health care landscape evolves, Battelle remains dedicated to advancing quality and reducing burden through continuous improvement and innovation.

In Fall 2023, Battelle introduced a streamlined 6-month E&M process that enhances consensus-building and ensures balanced participation.
Following public and interested party feedback, the Spring 2024 cycle saw significant improvements to increase engagement and reduce committee burden. Improvements included separate meetings for Advisory Groups, a Public Comment Listening Session for broader input, and a revised voting structure emphasizing the Recommendation Group's role.

During the 2024–2025 cycle for PRMR, the committee expanded from 155 to 175 members while maintaining patient and clinician representation. To enhance measure review and public comment collection, PRMR meetings were shifted to the beginning of the calendar year. This change led to a record number of public comments, with 239 written submissions and 51 verbal comments from 234 professional organizations and 56 patients/patient representatives. Listening sessions attracted over 458 attendees across three sessions.

In 2024, the MSR Recommendations Group evaluated 35 measures in the Affordability and Efficiency domain across 10 CMS programs. Unlike the previous MSR cycle, which focused solely on the End-Stage Renal Disease Quality Improvement Program (ESRD QIP), the 2024 cycle adopted a holistic, cross-program review approach. This was guided by the Cascade of Meaningful Measures, a tool that organizes the CMS measure portfolio around the eight priorities of Meaningful Measures 2.0. The group recommended discontinuing six measures and continuing 29, following an open and productive discussion with CMS that provided valuable feedback on each measure.

The CBE convened the CQMC Full Collaborative in late 2023 to set

priorities for the upcoming year. The goal of the meeting was to explore the CQMC's role in three key areas, including measurement in closing care gaps, movement to digital measures and alignment around measurement models. In addition, the CQMC discussed the leading barriers to adoption of measures within the core sets and achieving the desired impact of the core sets and how these can be overcome. The CQMC also began to develop a vision and strategy for the next phases of work. In October 2024, Battelle hosted the CQMC Full Annual Strategic Meeting to review progress and set priorities for the coming year. As of December 2024, the core measure sets include:

- Accountable Care Organizations;
- Patient-Centered Medical Homes;
- Primary Care;
- Behavioral Health;
- · Cardiology;
- Gastroenterology;
- HIV & Hepatitis C;
- Medical Oncology;
- Neurology;
- Obstetrics & Gynecology;
- · Orthopedics; and
- · Pediatrics.

HHS and the CBE both recognize the importance of clinical quality and cost/ resource use measures in improving U.S. health care. Maintaining these measures through transparent, periodic, and consensus-based reviews is critical for ensuring health care quality performance can not only be measured but can also be improved upon. The CBE is dedicated to building essential relationships within the health care quality community, including patients and clinicians, for advancing the national goal of attaining the highest level of health and wellness for the widest range of individuals possible.

### III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

#### IV. Addendum

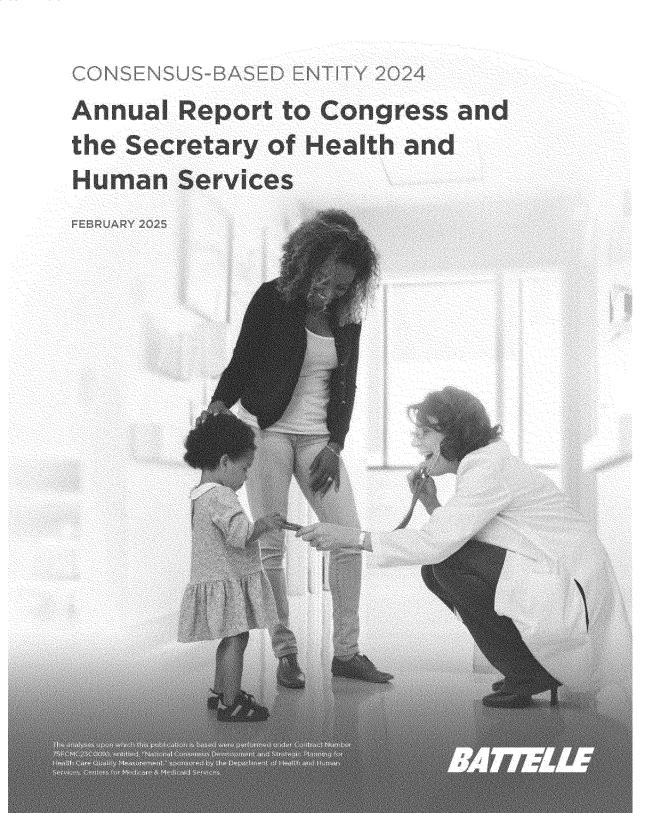
In this Addendum, we are publishing the CBE Report on 2024 Activities to Congress and the Secretary of the

<sup>&</sup>lt;sup>1</sup>HHS Strategic Cross-Cutting Principles available at https://www.hhs.gov/about/strategic-plan/2022-2026/overview/index.html.

Department of Health and Human Services, as submitted to HHS.

**Robert F. Kennedy, Jr.,**Secretary, Department of Health and Human Services.

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### **EXECUTIVE SUMMARY**

Battelle, the world's largest independent, not-for-profit applied science and technology organization, has over 30 years of experience advancing the science and translation of health care quality. As a certified consensus-based entity (CBE), Battelle launched the Partnership for Quality Measurement (PQM)™, a membership comprising over 1,200 health care stakeholders. The purpose of this report is to provide Congress and the Secretary of the Department of Health and Human Services (HHS) an update on the work accomplished by Battelle's CBE from January 1, 2024, to December 31, 2024.

#### **KEY OBJECTIVES AND ACHIEVEMENTS**

Vision for Quality Measurement: The vision of PQM is to establish a measure review process that is reliable, transparent, attainable, objective, and meaningful. This aligns with Battelle's commitment to engaging all populations in health care quality improvement.

Accessible Membership: PQM includes a wide range of health care voices, such as patients, caregivers, health care providers, measure experts, policymakers, and health IT specialists. Membership is free, promoting broad participation.

Shaping the Future of Health Care Quality: PQM members play a pivotal role in shaping the future of health care quality measurement. By leveraging their health care experiences and professional expertise,

they actively participate in the quality measurement process. Members review and provide feedback on quality measures that HHS is considering for use in Medicare programs. They serve on committees that evaluate these measures for endorsement, focusing on supporting evidence, scientific rigor, feasibility for implementation, and their importance to patients and clinicians.

Advancements in 2024: In 2024, Battelle's CBE enhanced its focus on advancing measurement science, ensuring transparency, and increasing the number of perspectives engaged in the process. This has led to greater involvement from patients, advocacy groups, and clinicians, fostering a shared sense of ownership and commitment to quality improvement.

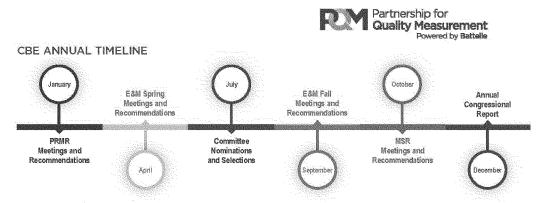


Figure 1. The CBE Annual Timeline

Battelle's annual CBE schedule begins with Pre-Rulemaking Measure Review (PRMR) in January, followed by two cycles of Endorsement and Maintenance (E&M), and rounds out with the Measure Set Review (MSR) at the end of the year. Throughout the year, Battelle also supports the Core Quality Measures Collaborative (CQMC). Each of these activities plays a critical role in creating a balanced portfolio of quality measures available to the health care field.

Endorsement and Maintenance (E&M) of clinical quality measures: Battelle convenes PQM committee members to evaluate quality measures submitted for endorsement or up for routine maintenance. Committee members answer the question: is the measure safe and effective for general use, and unlikely to result in negative unintended consequences?

Pre-Rulemaking Measure Review (PRMR): Battelle convenes PQM committee members to review measures submitted to CMS as part of the pre-rulemaking process. Committee members answer the question: is the measure reasonable and necessary for use in the intended CMS value-based program(s)?

Measure Set Review (MSR): Battelle convenes PQM committee members to review measures within the CMS portfolio of active measures. Committee members answer the question: is the measure aligned with CMS's current needs and priorities?

Core Quality Measures Collaborative (CQMC): Battelle partners with CMS and the American Health Insurance Plans (AHIP), as part of a public-private partnership, tasked with aligning quality measures across payors to reduce burden on clinicians.

#### THREE DISTINCT PROCESSES (AND DECISIONS):

# Endorsement & Maintenance (E&M)

#### Consensus-based endorsement of measure

- "Safe and effective"
- Use of the measure in health care will increase the likelihood of desired health outcome (net benefit)

#### Pre-Rulemaking Measure Review (PRMR)

### Recommendation to add measure to program

- "Reasonable and necessary"
- Consider the context of specific CMS program and population of CMS entities and beneficiaries

#### Measure Set Review (MSR)

#### Recommendation to remove measure from program

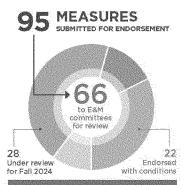
- "Market optimization"
- Explicit consideration of trade-offs in measure implementation experience, benefit, and burden within a measure domain

Figure 2. The Three CBE Processes

Endorsement and Maintenance:
Battelle's Endorsement and
Maintenance (E&M) process ensures that health care performance
measures are evidence-based,
scientifically sound, and effective
in improving health outcomes. The
E&M committees rigorously evaluate measures to ensure they are
reliable, valid, actionable, and relevant to the intended populations
and health care settings.

In Fall 2023, Battelle introduced a streamlined 6-month evaluation process, which also enhances consensus-building and ensures balanced participation. Following feedback, the Spring 2024 cycle saw significant enhancements to increase engagement and reduce committee burden. Improvements included separate meetings for Advisory Groups, a Public Comment Listening Session for broader input, and a revised voting structure emphasizing the Recommendation Group's role.

During 2024, over 95 measures were submitted to Battelle for endorsement consideration, of which 66 went to E&M committees for review due to measures being withdrawn after cycle launch or retired (maintenance measures only). E&M committees endorsed 31 measures during the Fall 2023 and Spring 2024 cycles, 22 of which were endorsed with conditions. Measures evaluated during the Fall 2024 cycle will receive final endorsement decisions in February 2025.



31 TOTAL MEASURES ENDORSED

Measures submitted for endorsement addressed critical areas like patient safety, clinical effectiveness, health access, and cost reduction. The E&M committee identified gaps in quality measurement and provided feedback on how the process could further evolve. In addition to committee feedback, Battelle also identified the need for better guidance in developing measure logic models, quantifying burden and explaining the value of a measure on the system. As the health care landscape evolves, Battelle is dedicated to advancing quality and reducing burden through continuous improvement and innovation.

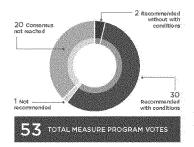
#### FEEDBACK RELATED TO 2024 E&M CYCLE ENHANCEMENTS

- "I enjoyed the process of how the Recommendation meeting was conducted, the conversation was facilitated, and ultimately how the measure went through voting process. We support the continuation of the rigorous criteria used to develop and evaluate measures."
- "[I liked most] the iterative improvements that Battelle made, including allowing developers to respond to public comment. The patient representative and SME [subject matter expert] leading conversations on measures during the Recommendation Group meeting created a nice flow to the facilitation of the measure discussion."
- "This was one of the best and most complex discussions that I have ever been in on in at least 15 years."

Pre-Rulemaking Measure Review (PRMR): Battelle leads the Pre-Rulemaking Measure Review (PRMR) process to make informed recommendations on quality and efficiency measures, aligning with section § 1890A of the Social Security Act. This process supports consensus recommendations for measures considered by the Centers for Medicaid & Medicare Services (CMS) for quality reporting and value-based programs. Due to the federal pre-rulemaking process spanning the calendar year, this report references 2023 activities to provide context for the 2023-2024 PRMR cycle conclusion.

In 2023, the PRMR committee comprised 155 members, including 20 patients and 39 clinicians. Battelle synthesized public comments and initial committee feedback to facilitate three setting-specific meetings on MUC List measures in January 2024. Committees recommended 32 measures for rulemaking, with 2 recommended without conditions and 30 recommended with conditions, such as requiring CBE endorsement before implementation. One measure was not recommended, and consensus was not reached on 20 measures.

For the 2024-2025 cycle, the committee expanded to 175 members, maintaining patient and clinician representation (Figure 3). To enhance measure review and public comment collection, PRMR meetings were shifted to the beginning of the calendar year. This change led to a record number of public comments, with 239 written submissions and 51 verbal comments from 234 professional organizations and 56 patients/ patient representatives. Listening sessions attracted over 458 attendees across three sessions.



- · Meaningfulness: Does the measure meet criteria for importance, scientific soundness, feasibility, and usability for the intended population and program?
- Appropriateness of scale: Is the measure applied in a way that maximizes its value across different segments of the target population?
- · Time to value realization: Does current evidence show a clear path from measurement to performance improvement?

In April 2024, Battelle hosted the 2024 PQM Measure Strategy Summit in Baltimore, MD. This event gathered PRMR/Measure Set Review (MSR) committee members to review the 2023-2024 PRMR cycle, discuss the PQM measure strategy and CMS priorities, and gather input for the 2024 MSR cycle.

Based on feedback from committees and CMS, Battelle implemented several changes for the 2024-2025 PRMR cycle. These include clearer definitions for "recommendation with conditions." increased committee size to reduce "consensus not reached" outcomes, a more defined role for the Advisory Group, and clarified voting procedures for instrument-based measures.









**Clinician** Members



Patient Co-Chairs

Figure 3. Committee Composition



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

The MSR process builds consensus around measure continuation to optimize the CMS measure portfolio in the value-based programs.

Measure Set Review (MSR): The Measure Set Review (MSR) process implemented by Battelle focuses on optimizing the CMS measure portfolio by reviewing measures across various programs. The goal is to ensure that measures continue to meet program needs and priorities, based on updated information about their properties and performance trends. This process builds consensus around which measures should continue to be used in value-based programs.

In 2024, the MSR Recommendation Group evaluated 35 measures in the Affordability and Efficiency domain across 10 CMS programs. Unlike the previous cycle, which focused solely on the End-Stage Renal Disease Quality Improvement Program (ESRD QIP), the 2024 cycle adopted a holistic, cross-program review approach. This was guided by the Cascade of Meaningful Measures, a tool that organizes the CMS measure portfolio around the eight priorities of Meaningful Measures 2.0. The group recommended discontinuing six measures and continuing 29, following an open and productive discussions with CMS that provided valuable feedback on each measure.

The MSR process evaluates measures based on three key domains:

- Meaningfulness: Ensures measures meet criteria for importance, feasibility, scientific acceptability, and usability across programs and populations.
- Data Stream Parsimony: Identifies and reduces redundancy in data streams.
- Patient Journey: Confirms measures are implemented as intended across the patient journey.

During discussions, members expressed interest in advancing focus on social determinants of health, allowing flexibility in measure specifications for personalized medicine, and considering the unique needs of rural communities. They also explored ways to enhance measure utility for patients and measured entities.

### FEEDBACK RECEIVED FROM PATIENT PARTICIPANT ABOUT THE 2024 MSR RECOMMENDATION GROUP MEETING:

"Thanks Battelle and CMS for making patients voice meaningful and making sure that our voice is heard. The last 2 years, our voice has taken on new meaning. It has been accepted and valued so much more than it was before. I feel that every day and in everything I do. All this measurement gets out in the world we live in. It is important to the world we live in as patients. I appreciate everything you do to make sure our voice is heard. I thank you from the bottom of my heart, it means the world to me. It means we have a better chance of a safer world for patients."

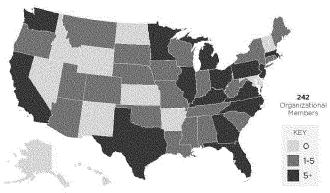
### Core Quality Measures Collaborative (CQMC):

The Core Quality Measures
Collaborative (CQMC) is a coalition
of health care leaders dedicated to
aligning measures across payers by
developing core sets of measures to
assess health care quality in the United
States. These core sets are organized
around specific conditions or topics
and can be implemented collectively
or selectively by users in the field.
In October 2024, Battelle hosted the
CQMC Full Annual Strategic Meeting to
review progress and set priorities for
the coming year.

#### Partnership for Quality

Measurement (PQM): PQM members cover 98 percent of the United States. Committee members represent a cross-section of the nation, hailing from urban, rural, and suburban communities across various socioeconomic backgrounds (Figure 4).

#### PQM ORGANIZATIONAL MEMBERSHIP MAP



#### Members Include:

#### Clergy

Consumer/Purchaser Advocates
Health Systems
Health Care Consulting
Hospitals
Life Science
Medical Groups
National Associations
Non-Profit Organizations
Nursing Specialties

Patient Advocacy
Patient Safety Activists
QIN-QIO
Rural Health Organizations
Specialty Trade Associations
Specialty Societies
State Government
State Hospitals
Voluntary Health Association

Figure 4. PQM Organizational Membership Map

**Summary.** In 2024, Battelle continued its vital role in enhancing U.S. health care by leveraging over 30 years of expertise as the world's largest independent, not-for-profit applied science organization. Through the Partnership for Quality Measurement (PQM), Battelle engaged over 1,200 stakeholders to drive improvements in health care measurement. Key initiatives focused on burden reduction, health access, patient safety, and digital quality measures. These efforts ensured a balanced and effective portfolio, underscoring Battelle's commitment to transparent, reliable, and meaningful processes. By fostering strong relationships within the health care quality community, Battelle remains dedicated to advancing the national mission of achieving optimal health and well-being for all.



### 1.0 Introduction

#### 1.1 Background

Battelle is the world's largest independent, not-for-profit applied science and technology organization, renowned for its commitment to innovation and excellence. Our mission is to translate scientific discoveries and technological advances into tangible societal benefits, addressing complex challenges across various sectors. In 2023, Battelle was awarded the National Consensus Development and Strategic Planning for Health Care Quality Measurement contract (NCDC) by the Centers for Medicare & Medicaid Services (CMS), aligning seamlessly with our ongoing efforts to enhance health care quality measurement and improvement.

The Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) introduced section § 1890 of the SSA and mandated the Secretary of the HHS to contract with a consensus-based entity (CBE) to synthesize evidence and convene key stakeholders to make recommendations focused on improving health care system performance, Activities include reviewing and endorsing standardized health care performance measures and reassessing previously endorsed measures. Section 3014 of the Patient Protection and

Affordable Care Act (ACA) further expanded the CBE duties to include convening stakeholder groups for input on selecting quality measures for input on selecting quality measures for public performance reporting and value-based programs. A further evolution of the CBE's role has included the recent addition of convening stakeholders to provide CMS with guidance on measures that should be considered for removal from its programs.

The NCDC's scope aligns with the requirements outlined in §1890 of the SSA. Battelle collaborates closely with CMS to fulfill the CBE's statutory goals through key initiatives (Figure 5):

- Endorsement and Maintenance (E&M) of clinical quality measures: Battelle convenes PQM committee members to evaluate quality measures for endorsement or routine maintenance, ensuring they are safe, effective, and unlikely to cause negative unintended consequences.
- Pre-Rulemaking Measure Review (PRMR): Battelle
  assembles PQM committee members to review
  measures submitted to CMS during the pre-rulemaking process, determining if they are reasonable and
  necessary for intended CMS value-based programs.
- Measure Set Review (MSR): Battelle gathers PQM committee members to assess measures within the CMS portfolio, ensuring alignment with CMS's current needs and priorities. If misaligned, the committee may recommend measure removal.
- Core Quality Measures Collaborative (CQMC):
   In partnership with CMS and the American Health Insurance Plans (AHIP), Battelle participates in a public-private partnership to align quality measures across payers, reducing the burden on clinicians.

#### THREE DISTINCT PROCESSES (AND DECISIONS):

#### Endorsement & Measure Set Pre-Rulemaking Maintenance Measure Review Review (E&M) (MSR) (PRMR) Consensus-based Recommendation to Recommendation to remove measure from endorsement of measure add measure to program program · "Safe and effective" "Reasonable and "Market optimization" necessary' · Use of the measure in · Explicit consideration health care will increase · Consider the context of of trade-offs in meathe likelihood of desired specific CMS program health outcome (net and population of CMS sure implementation experience, benefit, and benefit) entities and beneficiaries burden within a measure domain

Figure 5. The Three CBE Processes

#### 1.2 Partnership for Quality Measurement (PQM)

To facilitate comprehensive measure reviews, Battelle, as a consensus-based entity (CBE), established the Partnership for Quality Measurement (PQM). This partnership brings together an array of health care voices, including patients and caregivers, health care providers (such as clinicians, health plans, and health systems), measure experts (including developers, stewards, and

researchers), policymakers, measure implementers, and health information technology specialists. The vision of PQM is to create a measure review process that is reliable, transparent, attainable, and meaningful. To reduce barriers to participation in consensus-based work, Battelle offers membership in PQM at no cost.

PQM members cover 98 percent of the United States. Committee members represent a cross-section of the nation, hailing from urban, rural, and suburban communities across various socioeconomic backgrounds (Figures 6 and 7).

#### PQM ORGANIZATIONAL MEMBERSHIP MAP



#### Members Include:

**Nursing Specialties** 

Clergy
Consumer/Purchaser Advocates
Health Systems
Health Care Consulting
Hospitals
Life Science
Medical Groups
National Associations
Non-Profit Organizations

Patient Advocacy
Patient Safety Activists
QIN-QIO
Rural Health Organizations
Specialty Trade Associations
Specialty Societies
State Government
State Hospitals
Voluntary Health Association

Figure 6. PQM Organizational Membership Map

#### PQM INDIVIDUAL MEMBERSHIP

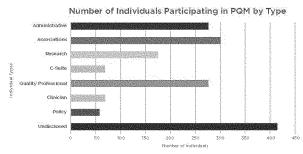


Figure 7. PQM Individual Membership

#### 1.3 Importance

Health care policy ideally improves population health and reduces health care workforce burden. Quality measures uniquely contribute to health care policy by identifying ways to enhance the health care system. While biomedical advances benefit us all, they often increase system costs. Quality measures ensure these advances benefit everyone and that resources are used efficiently.

Quality measures highlight barriers faced by patients, clinicians, and facilities, offering opportunities to leverage community insights to address these barriers. Battelle's approach to consensus-building through evidence-based policy and meaningful community engagement is designed to focus that attention and leverage that insight. As is described in this report, Battelle has continued to innovate in methods to assess evidence, to reduce burden, and to engage the community, with the ultimate goal of identifying the optimal portfolio of measures that society needs to ensure a healthy population and a robust heath care workforce.

#### 1.4 Audience

The primary audiences for this report are members of the U.S. Congress, congressional staff, the Secretary of HHS, and other government officials. Secondary audiences encompass parties interested in health care quality and efficiency measures, such as providers, patients, caregivers, insurers, and other payers. Additionally, measure developers; measure stewards; professional associations; policymakers; and those who research measurement science in academic, commercial, or private settings focused on measurement science are also key stakeholders.

#### 1.5 Report Organization

Pursuant to \$1890(b)(5)(A), the CBE is required to submit a report to Congress and the Secretary of HHS by March 1 of each year. Table 1 depicts the required content of the report and where it can be located.

Table 1. Contents of the 2024 Annual Report to Congress and the Secretary of HHS

ELEMENT	SECTION
The implementation of quality and efficiency measurement initiatives and the coordination of such initiatives with quality and efficiency initiatives implemented by other payers	3.0
Recommendations on an integrated national strategy and priorities for health care performance measurement;	2.0
Performance of the CBE's duties required under its contract with the Secretary	1.0
Gaps in endorsed quality and efficiency measures, including measures that are within priority areas identified by the Secretary under the national strategy established under \$399HH of the Public Health Service Act (National Quality Strategy), and where quality and efficiency measures are unavailable or inadequate to identify or address such gaps	3.0
Areas in which evidence is insufficient to support endorsement of quality and efficiency measures in priority areas identified by the Secretary under the National Quality Strategy, and where targeted research may address such gaps	3.0
The convening of multi-stakeholder groups to provide input on:  (1) the selection of quality and efficiency measures from among such measures that have been endorsed by the CBE and such measures that have not been considered for endorsement by the CBE but are used or proposed to be used by the Secretary for the collection or reporting of quality and efficiency measures; and	4:0), 5.0
(2) national priorities for improvement in population health and the delivery of health care services for consideration under the National Quality Strategy	
An itemization of financial information for the previous fiscal year ending September 30, including	8.0
Annual revenues of the entity	8.0
Annual expenses of the entity	8.0
A breakdown of the amount awarded per contracted task order and the specific projects funded in each task order assigned to the entity	8.1
Any updates or modifications to internal policies and procedures of the entity as they relate to the duties of the CBE	9.0
Any modifications to the disclosure of interests and conflicts of interests for committees, workgroups, task forces, and advisory panels of the entity	9.0
Information on external stakeholder participation in the duties of the entity	9.0

### 2.0 National Strategy

Pursuant to §1890(b)(1) of the SSA, the CBE must "synthesize evidence and convene key stakeholders to make recommendations, with respect to activities conducted under this Act, on an integrated national strategy and priorities for health care performance measurement in all applicable settings. In making such recommendations, the entity shall (A) ensure that priority is given to measures— (i) that address the health care provided to patients with prevalent, high-cost chronic diseases; (ii) with the greatest potential for improving the quality, efficiency, and patient-centeredness of health care; and (iii) that may be implemented rapidly due to existing evidence, standards of care, or other reasons; and (B) take into account measures that— (i) may assist consumers and patients in making informed health care decisions; (ii) address health disparities across groups and areas; and (iii) address the continuum of care a patient receives, including services furnished by multiple health care providers or practitioners and across multiple settings."

In 2024, Battelle's recommendations on national strategy come from several sources including the CBE portfolio, the CBE Quality Measurement Strategy, and recommendations made by stakeholders.

#### 2.1 Consensus-Based Entity Endorsement Portfolio

In 2023, Battelle launched the Partnership for Quality Measurement (PQM) website and the Submission Tool and Repository (STAR). STAR stores all measures that have been endorsed by a CMS funded consensus-based entity. In 2024, Battelle conducted an in-depth review of what measures were in the database to better determine to identify potential gaps.

The STAR database currently houses 1,245 quality measures submitted to a consensus-based entity. Previously, measures could receive various endorsement statuses, such as Endorsed for Trial

Use and Endorsed with Reserve Status. Battelle has consolidated measure status into three categories: Endorsed, Endorsed with Conditions and Not Endorsed.

As of June 2024, the STAR database includes 383 measures designated as endorsed; 36 measures endorsed with conditions and 825 measures not endorsed. Measures may not be endorsed for several reasons including: not receiving initial endorsement after committee review, endorsement not being retained during the maintenance review process, or a measure developer opting to resubmit a measure for a maintenance review.



CBE Measure Portfolio





Figure 8. STAR Portfolio

Each measure is assigned a measure type. Among the 419 measures endorsed or endorsed with conditions: 127 are outcome measures, 20 are intermediate outcome measures, 199 are process measures, 32 are patient-reported outcome measures, 18 are composite measures, 15 are cost measures and 8 are structural.

#### 2.2 Consensus-Based Entity Quality Measurement Strategy

Battelle seeks to support implementation of the requirements of \$1890 by leveraging CBE processes to focus quality measurement resources where they offer the most potential benefit for health care system change and where that benefit outweighs the burden of quality data collection, reporting, and use. In 2023, Battelle began the process of developing a 5-year CBE Quality Measurement Strategy. Elements of the strategy align with some of the most pressing issues surrounding quality measurement as well as emerging technologies or policies with the potential to improve quality measurement science.

#### Benefit for Health Care System Change

To support health care system change, quality measures should focus on areas where measurement is the most effective approach to improve the health of a population and reduce uncertainty about how to achieve high-quality care (Figure 9).

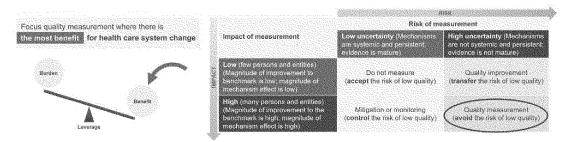


Figure 9. Strategy for Focusing Quality Measurement

The potential for improvement, known as "impact," is high when enhancing clinician or facility performance leads to a significant decrease in adverse outcomes or an increase in positive outcomes. On the other hand, the potential to reduce uncertainty, referred to as "risk," is high when low-performing clinicians or facilities are unsure about how to improve and whether they can overcome obstacles to improvement. By measuring performance, we can increase impact and decrease risk. This is achieved by emulating the successful strategies of high performers and identifying and addressing the barriers faced by low performers.

In 2024, Battelle started implementing the CBE Quality Measurement Strategy, focusing first on assessing risk and benefit at the individual measure and global portfolio levels. We now encourage measure developers to submit data on performance score distribution across clinicians or facilities by performance decile, known as the "Importance" table. Developers are also encouraged to provide a logic model and evidence explaining how high-performing clinicians or facilities achieve their results. By providing this information, measure developers can holistically explain the story and goal of their measure to a wide-ranging audience.

Although this strategy is in its early stages, it could significantly impact the number of measures endorsed or recommended for addition or removal in the CBE processes, thereby reducing burden on clinicians and patients. Measures that have been in use many years may struggle to demonstrate high impact for future use. Some measure developers may find it challenging in providing the required logic model and evidence. This challenge may disproportionately affect community-based developers or developers of pediatric or post-acute care measures. Battelle will carefully monitor this situation and provide technical assistance as needed.

Of particular note, assessing the impact of measures in the Quality Payment Program (QPP) presents a challenge due to the voluntary nature of reporting, which could incentivize high-performing clinicians to report. One potential solution is to collect performance data from a random sample of clinicians (e.g., 50 clinicians) to accurately assess the true underlying "epidemiological" performance in the target population.

The Burden of Quality Data Collection, Reporting, and Use

The CBE Quality Measurement Strategy not only addresses the impact and risk of measurement but also pursues direct approaches to assess the burden of quality data collection, reporting, and use. The literature defines "burden" as effort not directly applied to patient care. Recent years have seen modest growth in literature on the burden of data collection in health care. In the future, the CBE will request additional information on various aspects of burden, including costs associated with workflow modifications, data validation, and IT expenses (e.g., modifications or licensing).

There is a limited but consistent quantitative literature estimating the direct costs of quality data collection, reporting, and use. This information can help objectively assess the benefit-burden trade-off in measurement. The CBE plans to pilot potential metrics to inform the "return-on-investment" in quality measurement.

Together, the additional data collected through CBE processes on the benefit and burden of quality measurement will inform the endorsement, recommendation, and removal considerations made by PQM committees.

#### Assessing the Burden of Quality Data Collection, Reporting, and Use

Burden Category	Description  Time spent entering information or modifying workflows exclusively for quality reporting				
Data Entry Costs/Workflow Modification Costs					
<b>Guality Review Costs</b>	Costs associated with reviewing quality				
Metric Tracking Costs	Expenses for tracking quality metric specifications				
Development Costs	Costs of developing and implementing data collection processes				
Data Collection & Validation	Resources used in collecting and validating data				
Vendor Fees and Proprietary Fees	Includes both survey implementation fees, electronic health record (EHR) vendor fees for modifying templates, and any other priority (licensing) fees				
Training & Support Costs	Training staff to use new systems or follow new protocols				
Technology & Infrastructure	Expenses related to technological infrastructure, software, or tools required for data collection and reporting				
Miscellaneous Costs	Any other indirect costs related to administrative support, overhead, etc.				

#### 2.3 Recommendations from Stakeholders

As further explored in <u>Section 5.0</u>, the MSR process for 2024 gathered consensus recommendations from interested parties for the continued use of 35 Cost Effectiveness and Efficiency in Health Care Utilization measures from 10 CMS programs. During the MSR meeting, Recommendation Group members identified several recurring themes for future measure revisions and improvements, including:

- Prioritizing effective measures for rural communities.
- Balancing program requirements, measure performance, and participation.
- · Incorporating social determinants of health.
- Assessing measure performance across subgroups.
- Exploring new care coordination and communication measures.
- Exploring new patient-reported outcome performance measures.
- Promoting alignment across settings and programs.



Figure 10. Areas for Future Consideration



#### Prioritize Effective Measures for Rural Communities Prioritize Effective Measures for Rural Communities

Throughout the MSR meeting, members emphasized the need to prioritize effective measures for rural communities, highlighting challenges such as:

- · Lack of outpatient specialty care
- · Low patient volume
- · Limited social support services
- · Geographic barriers
- Higher burden of social determinants of health (SDOH)

#### Key recommendations included:

- Stratifying performance data to assess rural providers separately.
- Involving rural facilities in measure development and including rural perspectives on technical expert panels (TEPs).
- Developing implementation guides and support for rural communities.
- Exploring rural-focused MIPS Value Pathways or measure sets to address performance gaps.

These steps aim to ensure that rural providers can meet CMS performance benchmarks and improve health care outcomes in these communities.



# Incorporate Social Determinants of Health (SDOH)

Committee members are increasingly interested in how social determinants of health (SDOH) affect measure implementation and performance across populations. SDOH include factors like economic stability, education, health care access, neighborhood environment, and social context. Concerns were raised about rural and low-resource facilities, where negative SDOH factors can lead to lower scores on readmission measures, despite readmission being necessary for patient care.

#### Key recommendations include:

- Incorporating SDOH data, such as dual eligibility for Medicaid and Medicare, into measure stratification or risk adjustment to avoid penalizing providers serving high-need populations.
- Recognizing that dual eligibility may not fully capture economic need due to regional Medicaid service differences.
- Encouraging CMS and developers to explore new methods for collecting patient-level SDOH data to improve risk adjustment and stratification.



### Explore New Care Coordination and Communication Measures

During discussions on imaging overuse measures, the committee emphasized the need for effective communication and coordination between community providers and radiologists at larger facilities. Key points include:

- Communication as a Barrier: Lack of communication hinders high performance on overuse measures.
- Measure Intent: Effective coordination between ordering providers and specialists is crucial for adhering to appropriate use guidelines.
- Direct Measurement: If the goal is to improve communication, measures should target communication and coordination processes directly.
- New Measures: CMS and developers should create measures promoting effective communication and coordination between specialists and facilities.
- Ongoing Evaluation: Use focus groups and interviews to ensure measures align with their original intent and address workflow issues.

These steps aim to enhance measure effectiveness by focusing on communication and coordination in health care settings.



Balance Program Requirements, Measure Performance, and Participation for Effective Measure Sets

During discussions on measure removal, committee members expressed concerns about limiting measures available for specialty providers. They argued for maintaining a minimum number of relevant measures, even if some are "topped out." Key points include:

- Measure Availability: Ensure enough measures for specialty providers to report, enabling fair participation.
- Program Mandates: Consider statutory requirements under the IMPACT Act and their impact on the measure set.
- Balancing Requirements: Balance program participation with measure appropriateness and effectiveness by:
  - Providing suitable measures for fair participation.
  - Ensuring measures are scientifically robust and allow performance improvement.
  - 3. Meeting statutory obligations.

The committee encouraged CMS to explore ways to balance participation and statutory requirements with measure effectiveness. This might involve keeping "topped-out" measures temporarily or phasing in new measures with innovative technologies like NLP. They also emphasized improving transparency in measure-performance monitoring to assure appropriateness, effectiveness, and balance across populations.



#### Assess Measure Performance Across Subgroups

Committee members showed interest in analyzing measure performance across subgroups, such as rural versus urban areas and different socioeconomic statuses. They expressed concerns that "topped out" measures might still offer improvement opportunities for certain providers. They emphasized exploring performance differences between high- and lowresource settings, noting that providers facing greater barriers might improve more slowly. They advised CMS to evaluate subgroup performance variations before phasing out measures. Concerns were also raised about facilities serving higher-need populations or acting as "safety net" providers, which might show lower performance due to factors like limited community services and a larger proportion of patients facing care barriers, lower health literacy, and higher comorbidity rates.



### Explore New Patient-Reported Outcome Performance Measures

The committee expressed interest in developing additional complementary patient-reported outcome performance measures (PRO-PMs) for discharge to community measures. These measures aim to provide an aligned patient perspective across different care settings on discharge planning and practices. They also suggested creating PRO-PMs to evaluate the extent of patient and family participation in discharge planning and shared decision-making. Beyond this measure group, the committee emphasized engaging patients, caregivers, and families in outcomes-based measures, focusing on improving patient participation in decision-making and care quality assessment.



#### Promote Alignment Across Settings and Programs Promote Alignment Across Settings and Programs

During discussions on readmission measures, the committee examined potential overlaps with measures in other programs. They support CMS's efforts to align or harmonize measures across programs and encouraged further alignment on risk-adjustment models. The committee emphasized the importance of considering cross-program contexts in future MSR cycles. While the program-specific focus during the 2024 MSR cycle ensured individual program contexts were considered, it did not allow for broader optimization of similar measure sets across programs. The committee challenged CMS and the CBE to more fully integrate a cross-program approach into the measure review process.

#### 2.4 Prioritized Measures Reviewed

In 2024, the CBE had the capacity to review all measures submitted for E&M, PRMR, and MSR. Table 2 provides a summary of measures reviewed fitting within the categories listed above.

Table 2. Crosswalk from National Priority Areas to PQM Activities in 2024

MEASURE PRIORITY (CATEGORY)	NUMBER OF MEASURES UNDER REVIEW IN 2024*			
	E&M*	PRMR	MSR**	
Address health care provided to patient with prevalent, high-cost chronic disease	18	9	8	
Greatest potential for improving quality, efficiency, and patient-centeredness of health care.	22	18	35	
May be implemented rapidly due to existing evidence, standards of care, or other reasons.	34	15	35	

<sup>&#</sup>x27;Measure counts across table rows are not mutually exclusive.

<sup>&</sup>quot;As of December 31, 2023, only measures in the Fall 2023 and Spring 2024 cycles had received endorsement decisions. The Fall 2024 cycle measures (n=39) will receive endorsement decisions in February 2025.

<sup>\*\*</sup>All MSR measures are currently implemented in CMS programs.

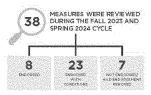
# 3.0 Implementation of Quality and Efficiency Measurement Initiatives (E&M)

Pursuant to \$1890(b)(2) of the SSA, the CBE shall "provide for the endorsement of standardized health care performance measures. The endorsement process under the preceding sentence shall consider whether a measure is (A) evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level; and (B) is consistent across types of health care providers, including hospitals and physicians." Section 1890 (b)(3) notes "the entity shall establish and implement a process to ensure that measures endorsed under paragraph (2) are updated (or retired if obsolete) as new evidence is developed." The CBE is required to describe the results of these processes pursuant to \$1890(b)(5)(i)(l) of the SSA.

Battelle's approach to the E&M process includes several enhancements made after its launch in Fall 2023:

- Increased Engagement: Organized separate meetings for the Advisory Group to enhance discussion before Recommendation Group endorsement meetings.
- Streamlined Voting: Revised voting requirements to make the process more efficient.
- Public Comment Sessions: Introduced Public Comment Listening Sessions to improve endorsement meeting efficiency and broaden participation in measure evaluation.
- Endorsement Results: Provided summaries of endorsement results for measures submitted in Fall 2023, Spring 2024, and Fall 2024 E&M cycles.
- Quality Measurement Gaps: Summarized quality measurement gap areas based on evaluations during these cycles.

In this section, we also provide summaries of the endorsement results of measures submitted to Battelle for the Fall 2023, Spring 2024, and Fall 2024 E&M cycles and summaries



of quality measurement gap areas based on the measure evaluations during these cycles.

Additional details about the E&M process can be found in the <u>E&M Guidebook</u> on the PQM website <u>www.p4qm.org</u>.

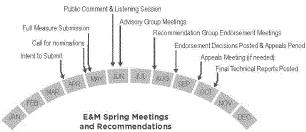


Figure 11, E&M Spring Timeline

# 3.1 Endorsement and Maintenance (E&M) Overview

The E&M process ensures that measures submitted for endorsement are:

- Evidence-Based: Measures are grounded in scientific research and current professional knowledge.
- Scientifically Sound: Measures are reliable and valid, producing consistent and credible results.
- Safe and Effective: Measures should increase the likelihood of desired health outcomes without increasing the risk of adverse outcomes.

During each E&M cycle, an E&M committee reviews submitted measures and decides on their endorsement status:

- Endorsed: Fully approved measures.
- Endorsed with Conditions: Measures are approved with specific conditions or actions recommended by the committee, such as additional evaluations or feedback mechanisms.
- Endorsement Removed: Applicable to maintenance measures only.
- Not Endorsed: Applicable to new measures only.

The "endorsed with conditions" category allows for endorsement with recommended actions for the developer to undertake before the next maintenance cycle, ensuring continuous improvement and alignment with health care goals.

Committees evaluate measures for endorsement across four required domains. The four domains are:

Importance: Extent to which the measure is evidence based AND is important for making significant gains in health care quality or cost where there is variation in or overall less-than-optimal performance.

Feasibility: Extent to which the measure specifications (i.e., numerator, denominator, exclusions) require data that are readily available OR could be captured without undue burden AND can be implemented for performance measurement.

Scientific Acceptability (i.e., Reliability and Validity): Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented.

**Use and Usability:** Extent to which potential audiences (e.g., consumers, purchasers, providers, and policymakers) are using or could use measure results for both accountability and performance improvement to achieve the goal of high-quality, efficient health care for individuals or populations.

Appendix D of the E&M Guidebook describe these domains and provide guidance on the interpretation and application of the PQM Measure Evaluation Rubric.

#### 3.2 Enhanced E&M Process

In the Fall 2023 cycle, Battelle made several enhancements to the E&M process, which were detailed in the 2023 Congressional report. These enhancements included streamlining the process to a 6-month timeline (Figures 11 and 14 [fall and spring timelines]).

In response to feedback from the Fall 2023 cycle, Battelle implemented several key enhancements for the Spring 2024 E&M cycle while maintaining the streamlined 6-month process and the attention on focused facilitation. These enhancements aim to improve engagement and participation, reduce burden, and clarify roles within the E&M process:

- Host Separate Advisory Group Meetings:
   To enhance engagement and allow Advisory Group members to ask questions and share feedback verbally.
- Conduct Public Comment Listening Sessions: To increase accessibility and public input before endorsement meetings.
- Change in Recommendation Group Size and Voting Requirements: To streamline decision-making and ensure balanced participation.

These updates are designed to enhance the engagement and participation of Advisory Group members and the public, reduce the burden on E&M committee members, and clarify the roles of the Advisory and Recommendation Groups (Figure 12).

#### 2024 ADVISORY AND RECOMMENDATION GROUPS

#### ADVISORY GROUP



#### RECOMMENDATION GROUP

- Review and Feedback: Members review measures and provide feedback and questions during Advisory Group meetings, which occur 1-2 months before the Recommendation Group endorsement meetings.
- Consensus-Building: They contribute to the consensus-building process by serving as the larger number of voices on the committee, Battelle shares their input with the Recommendation Group for review and discussion during the endorsement meetings.
- Review and Comment: Members review and provide ratings and written comments on measures before the Recommendation Group endorsement meetings.
- Feedback and Public Comments: They review the Advisory Group's feedback and questions, public comments, and responses from developers/stewards regarding the measures under review prior to the endorsement meetings.
- Endorsement Decision: They render an endorsement decision via a vote during the endorsement meetings.

Figure 12. Spring 2024 Cycle Enhancements: Roles of Advisory and Recommendation Group Members

#### 3.2.1 Added Advisory Group Meetings

To enhance the ability of Advisory Group members to raise questions and to verbally share perspectives regarding the measures under endorsement review, we convened separate meetings for the Advisory Group members for each committee 1–2 months prior to the endorsement meetings. Key elements of these meetings include:

- Measure Review: Advisory Group members reviewed assigned measures and participated in virtual meetings to discuss the strengths and limitations of the measures.
- Discussion and Feedback: Members were able to ask questions and provide comments, but endorsement voting did not occur during these meetings.
- Involvement of Other Stakeholders:
   Recommendation Group members and measure developers/stewards were invited and encouraged to attend these meetings to listen to the discussions.
- Summary for Consideration: The Recommendation Group received a summary of the Advisory Group's questions, feedback, and developer/steward responses to consider in advance of the E&M endorsement meetings.

This approach was designed to improve engagement and ensure that the Advisory Group's insights were effectively integrated into the endorsement process.

#### 3.2.2 New Voting Guidelines

In the Fall 2023 cycle, both the Advisory Group and Recommendation Group participated in voting during the E&M committee endorsement meetings. However, with the implementation of separate Advisory Group meetings, we adjusted the voting requirements so that only the Recommendation Group votes during the endorsement meetings. This change aligns with the PRMR process and reduces the potential burden associated with attendance and the risk of not meeting quorum, which can necessitate collecting votes offline.

To accommodate these changes, we increased the Recommendation Group size to 20-25 individuals by recruiting members from the respective E&M committee's Advisory Group to serve on the Recommendation Group for the Spring 2024 cycle. This increase in size helps maintain the balance of voices and perspectives, as outlined in the E&M Guidebook. For future cycles, we plan to replenish the full capacity of the E&M committees through the 2024 CBE nominations period.

Recommendation Group perspective goals are outlined in <u>Table 6</u> of the E&M Guidebook. More information about the nominations process for E&M committees can be found in the <u>E&M Guidebook</u>. Public Comments Related to the New E&M Process

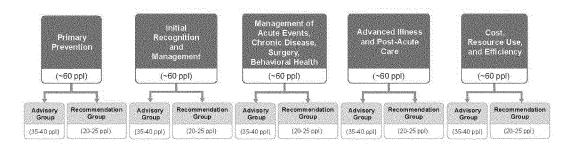


Figure 13. E&M Committee Structure

#### 3.3 Annual Endorsement Results

Between February 2024 and February 2025, Battelle convened E&M project committees to review and render endorsement decisions on quality and/or cost/resource use measures submitted to the Fall 2023, Spring 2024, and Fall 2024 E&M cycles. A total of 95 measures were submitted for endorsement consideration during this period. Of these, 56 measures were submitted to the Fall 2023 and Spring 2024 cycles. The E&M committees reviewed 38 of these 56 measures, while 18 measures were withdrawn due to requests from developers/stewards to defer measures to a future cycle or because the measure's endorsement was no longer maintained by the measure steward (as detailed in Table 3 and Table 4).

The remaining 39 of the 95 measures were submitted to the Fall 2024 cycle (as shown in Table 5). Because the Fall 2024 endorsement meetings are scheduled for February 2025, the results of these endorsement decisions will be included in next year's report.

#### **FALL 2023 CYCLE MEASURES**

The Fall 2023 cycle received a total of 27 measures, which included eight new measures and 19 maintenance measures. Of these, developers/stewards withdrew 11 measures due to requests to defer them to a future cycle or because they were no longer pursuing endorsement, as detailed in Table 3.

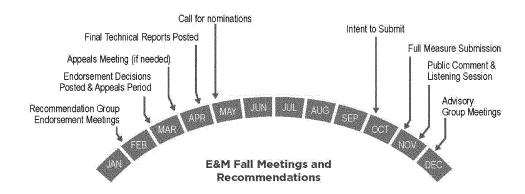


Figure 14. E&M Fall Timeline

Table 3. Overview of Fall 2023 CBE Endorsement Decisions by E&M Cycle and Project

E&M Project	Number of Measures Submitted	Number of Measures Reviewed	Number of Measures Withdrawn	Endorsement Decision Counts
				Endorsed: 5 (2 maintenance/3 new)
Fall 2023	27	16	11	Endorsed with Conditions: 6 (5 maintenance/1 new)
	Not Endorsed/Endorsement Removed: 5 (2 maintenance/3 new)			
	www.mediconorco.com/united/active/contrological-active	ALL PRODUCTS OF THE PRODUCTS O	es al anticologic colorino (resp. 103 a consultation) garage est de cinera colorino (resp. 104 a consultation (resp. 104 a consultation) est de cinera colorino (resp. 104 a consultation) est de ci	Endorsed: 0
Primary Prevention	3	1	2:	Endorsed with Conditions: 1
				Not Endorsed/Endorsement Removed: 0
				Endorsed: 0
Initial Recognition and Management	3:	3	0	Endorsed with Conditions: 1
management			_	Not Endorsed/Endorsement Removed: 2
Management of Acute		DO COMMONDE CONTRACTOR OF THE		Endorsed: 3
Events, Chronic Disease,	1)	5	.6	Endorsed with Conditions: 1
Surgery, and Behavioral Health				Not Endorsed/Endorsement Removed: 1
	oonorik moinida ini mooniy maayamaa saasaa ta maanaa			Endorsed: 1
Advanced Illness and Post-Acute Care	4	4	0	Endorsed with Conditions: 3
Lost-Acate, Cate.			-	Not Endorsed/Endorsement Removed: 0
A PRINCE OF THE REPORT OF THE REPORT OF THE PROPERTY OF THE PR		9221936093300043461225949430000A20009994000		Endorsed: 1
Cost and Efficiency	6	3	.3	Endorsed with Conditions: 0
			-	Not Endorsed/Endorsement Removed: 2

#### **SPRING 2024 CYCLE MEASURES**

The Spring 2024 cycle received a total of 29 measures, which included six new measures and 23 maintenance measures. Of these, developers/stewards withdrew seven measures due to requests to defer them to a future cycle, as detailed in Table 4.

In Spring 2024, six measures were submitted for endorsement review within Advanced Illness and Post-Acute Care category. Among these, <u>CBE #2967 – Home and Community-Based Services (HCBS) Consumer.</u>
Assessment of Healthcare Providers and Systems

(CAHPS®) Measure contains 19 individual measures. Per the Policy on Instrument-based Clinical Quality. Measures, the CBE does not endorse survey instruments. Rather, the CBE reviews and endorses measures derived from survey instruments in which survey assessments are aggregated to an accountable entity. Consequently, each of the 19 measures derived from the HCBS CAPHS survey instrument were reviewed and endorsed separately. Seventeen of the measures received an Endorsed with Conditions decision and the remaining two measures were not endorsed due to no consensus

Table 4. Overview of Spring 2024 CBE Endorsement Decisions by E&M Cycle and Project

E&M Project	Number of Measures Submitted	Number of Measures Reviewed	Number of Measures Withdrawn	Endorsement Decision Cou	nts
nt castal action of the common common of the common common common common common common common common common co	mana ta da di Pana anto da Malanda de Santa de S			Endorsed: (3 maintenance/1 new)	4
Spring 2024	29	22	7	Endorsed with Conditions: (15 maintenance/1 new)	16
				Not Endorsed/Endorsement Removed: (0 maintenance/2 new)	2
n 4 marko (1 marko ( 1 marko (1 marko (				Endorsed:	0
Primary Prevention	1	1	0 -	Not Endorsed/Endorsement Removed:	1
Filliary Frevention	ŧ-	1	0	Approved for Trial Use:	0
				Sent Back for Reconsideration:	О,
				Endorsed:	0
Initial Recognition and Management	6	4	2	Not Endorsed/Endorsement Removed:	2
and Hanagement			_	Sent Back for Reconsideration:	2
Management of Acute Events.				Endorsed:	4
Chronic Disease,	9	5	4	Not Endorsed/Endorsement Removed:	1
Surgery, and Behavioral Health			<del></del>	Sent Back for Reconsideration:	0
	CONTRACTOR OF THE STATE OF THE	at de maio de minimismo de porte de maio de presenta de la composição de l	омнического в втором больше больше больше строи. Ангарического строи для политического в общений в общени	Endorsed:	0
Advanced Illness and Post-Acute Care	6*	6*	0	Endorsed with Conditions:	6
1 ose / louises gare			*****	Not Endorsed/Endorsement Removed:	0
физиков на менения выборя для выполняющих выпользований для выполняющих выстранции выполняющих выстранции выполняющих выполнающих выстрации выстратичения выстратичения выстратичения выстратичения вы		arukta elebinni tuonnaksaturbekin tuonaksaksettetti selebikis dahku	ektroven dalarbiteket zerisummen en ektronen autoria antekniste eta eta eta eta eta eta eta eta eta e	Endorsed:	0
Cost and Efficiency	7	6	1	Endorsed with Conditions:	
			° was	Not Endorsed/Endorsement Removed:	

<sup>\*</sup>For this cycle, six measures were submitted for endorsement review; however, CBE #2967 – Home and Community-Based Services (HCBS) Consumer: Assessment of Health care Providers and Systems (CAHPS®) Measure contains 19 individual measures. Per the Policy on Instrument-based Clinical Quality Measures, the CBE does not endorse survey instruments. Rather, the CBE reviews and endorses measures derived from survey instruments in which survey assessments are aggregated to an accountable entity. Thus, each of the 19 measures derived from the HCBS CAPHS survey instrument is reviewed and endorsed separately. Seventeen of the measures received an Endorsed with Conditions decision and the remaining two measures were not endorsed due to no consensus.

#### **FALL 2024 CYCLE MEASURES**

The Fall 2024 cycle received a total of 39 measures, which included 24 new measures and 15 maintenance measures, as detailed in Table 5. During this cycle, developers/stewards withdrew two measures: one was deferred to a future cycle, and the other was combined with another Fall 2024 measure due to a similar measure focus but different care setting. The five E&M project committees are scheduled to render endorsement decisions for these measures in February 2025, and the results will be incorporated into next year's report.

Table 5. Overview of Fall 2024 CBE Endorsement Decisions by E&M Cycle and Project

E&M Project	Number of Measures Submitted	Number of Measures Reviewed	Number of Measures Withdrawn	Endorsement Decision Counts
Fall 2024	39	28	11±	To be determined in February 2025
Primary Prevention			: O.	To be determined in February 2025
Initial Recognition and Management	8.	5	3±	To be determined in February 2025
Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health	·11	-11	0	To be determined in February 2025
Advanced Illness and Post-Acute Care	15	8	7	To be determined in February 2025
Cost and Efficiency	. 4	3		To be determined in February 2025

<sup>±</sup> For the Fall 2024 cycle, developers/stewards withdrew two measures; one was deferred to a future cycle and the other was combined with another Fall 2024 measure due to a similar measure focus but different care setting.

### 3.4 Quality Measurement Gap Areas and Evidence Needs

In addition to the enhancements to the E&M process, the E&M committee identified several key themes in their reviews, highlighting gaps in quality measurement and the need for more robust evidence. The committee emphasized the importance of developing measures that capture the maintenance of a person's function—defined as their ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being-not just improvement. They also advocated for expanding outpatient procedural measures to include younger (i.e., those under 65 years of age) Medicare Advantage and Medicare fee-for-service patients, as well as extending substance use disorder treatment measures to individuals under 18 years old). The committee also noted the role of pharmacists in the care delivery process as crucial and underscored the need for their services to be included in measurement. Currently, pharmacists are not considered eligible providers under the Social Security Act and thus cannot seek direct reimbursement for certain services. Therefore, pharmacists are not generally reflected in measures.

Furthermore, there is a recognized need from the quality measurement community for enhanced guidance for developers/stewards in creating effective measure logic models and expansion of evaluation domains. To address these needs, Battelle is developing comprehensive guidance to assist developers/stewards in designing logic models that clearly delineate the pathway from measure inputs to desired outcomes, ensuring that measures not only adhere to high standards of effectiveness and safety but also actively contribute to reducing health disparities.



#### 3.4.1 Quality Measurement Gap Areas

Maintenance of Function vs. Improvement: The Advanced Illness and Post-Acute Care committee reviewed several measures that focused on improvement in function related to ambulation (CBE #0167), bathing (CBE #1074), bed transferring (CBE #0175), and medication management (CBE #0176) in the home care setting. The committee emphasized the value of measures that monitor both maintenance and improvement of function. Both the Advisory and Recommendation Groups discussed the complexity of improvement, describing it as a multidimensional concept. They noted that individuals may have mobility issues for various reasons, requiring different care approaches. The Recommendation Group further highlighted that improvement can sometimes lead to negative consequences for some individuals, making maintenance a more appropriate goal. The developer acknowledged the importance of maintaining versus improving and has begun incorporating this concept into new measures, including a cross-setting discharge function measure for inpatient rehabilitation facilities (IRF), skilled nursing facilities (SNF), long-term acute care hospitals (LTACH), and home health, finalized in last year's home health final rule. However, the committee stressed the importance of having measures relevant to home health patients for whom improvement is not expected.

Adding Medicare Advantage Beneficiaries and Those Less than 65 Years of Age: During the review of several outpatient procedure measures focusing on hospitalizations after general surgery (CBE #3357), urology surgery (CBE #3366), orthopedic surgery (CBE #3470), and colonoscopy (CBE #2539), the Cost and Efficiency committee discussed the importance of including Medicare Advantage patients and patients under the age of 65 in the measure population. Recommendation Group members expressed disappointment that the measure population excluded Medicare Advantage patients, whose numbers are growing. The developer explained that data on Medicare Advantage patients were not included due to limited availability and that expanding the measure's population requires approval and resource allocation by CMS.

Regarding Medicare patients under 65, patient partners questioned their exclusion. Recommendation Group members acknowledged that these patients often have different health statuses, complex conditions, and disabilities, which could skew results. The developer noted that including those under 65 poses challenges due to their higher burden of disability, complicating risk adjustment. Additionally, the proportion of under-65 Medicare patients receiving procedures in ambulatory surgical centers (ASCs) is lower, suggesting that adding this population might be more relevant in inpatient and hospital outpatient department (HOPD) settings.

Recognizing the importance of both populations, Recommendation Group members suggested further exploration of the ASC population to determine if Medicare patients under 65 frequently use ASCs for these procedures. They also recommended that the developer and CMS consider expanding the measure to include the Medicare Advantage population.

Acknowledge Pharmacists as Providers: During the review of CBE #3455 Timely Follow-Up After Acute Exacerbations of Chronic Conditions, the Management of Acute Events and Chronic Conditions committee suggested expanding visit eligibility in the measure to include pharmacist-led visits and Medicare Wellness visits. They also questioned whether provider types could be specifically identified. The developer responded by explaining that the measure allows a wide range of providers to fulfill the follow-up visit requirement, with over 180 codes covering various visit types, such as rehabilitation, behavioral health, telehealth, and home visits. However, committee members highlighted that pharmacists are excluded from being recognized as providers. They expressed that this exclusion limits the ability to fully capture pharmacists' contributions to patient care, potentially undermining comprehensive care delivery.

Importance of Expanding Continuity of Care to Other Populations: During its review of CBE #3453 Continuity of Care After Inpatient or Residential Treatment for Substance Use Disorder, the Advanced Illness and Post-Acute Care committee recognized the importance of ensuring follow-up treatment services for individuals discharged for substance use disorder (SUD). However, both the Advisory and Recommendation Groups emphasized the need to expand the measure to include individuals under 18 years of age and those with private insurance. Currently, the measure is limited to Medicaid beneficiaries aged 18-64 due to the scope of the developer's contract. Expanding to other payers and patient populations requires approval and resource allocation by CMS. The committee stressed that broader use of the measure would increase continuity of care for more individuals, especially those disproportionately affected.

#### 3.4.2 Evidence Needs

Logic Model Guidance: Under Battelle's E&M process, measure developers and stewards must provide a logic model that succinctly outlines how specific inputs and activities lead to desired outcomes and impacts related to quality improvement. The measure focus should generally align with an outcome, regardless of the measure type (e.g., structure, process, outcome). The logic model serves as a framework to increase the likelihood of achieving the measure's focus by considering the most plausible investments and actions, while also accounting for potential feedback loops, key assumptions, and external factors. A lack of a clear measure logic model often challenges reviewers in understanding how the measure fits into an overall quality construct and aligns with the measure's intent during validity testing.

The Blueprint Measure Lifecyle content on the MMS Hub provides general guidance in related areas such as information gathering and business case development, but it does not directly address development of measure logic models. To address this gap, we are developing guidance to support measure developers and stewards in creating comprehensive and effective logic models. This guidance will include best practices for identifying and defining key components of the logic model, such as inputs, activities, outputs, outcomes, and impacts. It will also offer strategies for incorporating feedback mechanisms and considering external factors that may influence the measure's success. Additionally, the guidance will provide examples of well-constructed logic models to help developers and stewards visualize and understand the components and relationships within their measures. By enhancing the clarity and effectiveness of measure logic models, we aim to improve the ease of review and the overall quality of measures endorsed under Battelle's process. This initiative will ultimately contribute to more targeted and impactful quality improvement efforts within the health care system.

Responsive to Variations: Pursuant §1890(b)(2) of the SSA, the CBE shall consider if measures are responsive to variations in patient characteristics, Battelle has engaged stakeholders in understanding how quality measurement can improve quality, reduce burden, and prevent unintended consequences. Health care quality measurement is essential for evaluating and enhancing the performance of health care providers and systems in the U.S., ensuring that patients receive safe, effective, and patient-centered care.

Despite its importance, traditional quality measurement continues to face challenges in fully addressing variations in health outcomes among different subpopulations. Battelle's E&M process reviews measures for endorsement consideration to ensure they are evidence-based, scientifically sound, and both safe and effective. This means the use of the measure will increase the likelihood of desired health outcomes, will not increase the likelihood of unintended adverse health outcomes, and is consistent with current professional knowledge. To that end, during the Fall 2023 E&M cycle developers and stewards were asked to describe how their measure contributes to advancing health across sub-populations.

To support developers and stewards in addressing this challenge, we are developing guidance to assist them in effectively incorporating these considerations into their measures. Battelle aims to ensure that measures not only meet high standards of effectiveness and safety but also actively contribute to reducing variations in health outcomes due to patient characteristics.

## 4.0 Multi-Stakeholder Engagement: Pre-Rulemaking Measure Review (PRMR)

Section 1890A(a) of the SSA states "The Secretary shall establish a pre-rulemaking process under which the following steps occur with respect to the selection of quality and efficiency measures described in §1890(b)(7)(B)." Pursuant to §1890(b)(7), the entity with a contract under §1890 (Battelle) shall convene multi-stakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures described in subparagraph (B).

Pursuant to \$1890A(2), the Secretary of HHS is required to publish a list of quality and efficiency measures being considered for a CMS program. Battelle convenes stakeholders to review and make recommendations on the published measures. By February 1, Battelle must publish those recommendations.

Battelle convenes stakeholders for the purpose of making recommendations on the selection of quality and efficiency measures in accordance with the statute via the PRMR process. In a separate but related MSR process, Battelle convenes stakeholders to consider measure discontinuation.

#### 4.1 Pre-Rulemaking Measure Review (PRMR) Overview

The PRMR process is conducted annually to provide recommendations to HHS on selecting quality and efficiency measures under consideration (MUC) for use by HHS. This process supports consensus recommendations, on each measure, to CMS quality reporting and value-based programs. A measure is deemed appropriate for use in a specific CMS program and population of Medicare beneficiaries

(e.g., Skilled Nursing Facility Quality Reporting Program) if it is:

- · Meaningful
- Tailored to specific program or population needs
- Balanced and scaled to meet program-specific goals
- Demonstrates a clear vision of near- and long-term program impacts

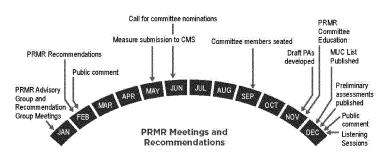


Figure 15. PRMR Timeline

The Measures Management System website (MMS Hub) provides detailed information on the process, purpose, and timeline of the MUC process.

While the PRMR and MSR processes are similar in approach, they have distinct goals and purposes, as shown in Table 6 and Figure 16. Both processes are structured to foster collaboration and balance the input of various interested parties, enabling committees to generate well-informed recommendations regarding measures to be included or removed from a specific CMS reporting program.

**PRMR Process:** The primary objective is to assess the appropriateness of the measures included on the MUC List, specifically in the context of the program and population for which they are being considered. It is structured to ensure collaboration and focus on specific programs and populations.

MSR Process: In contrast, the MSR process conducts a voluntary review of the relative strengths and weaknesses of CMS's current measure portfolio. It evaluates how the removal of an individual measure would reduce redundancy or create a measurement gap. Compared to the PRMR process, the MSR process is less structured, allowing for a more holistic review involving qualitative assessment of portfolios of measures across programs, guided by input from interested parties (Figure 16). The MSR process is detailed further in <u>Section 5.0</u> of this report.

Table 6. Overview of PRMR and MSR Processes

	Pre-Rulemaking Measure Review (PRMR)	Measure Set Review (MSR)
Goal	To achieve consensus regarding MUC list measures as to whether they are reasonable and necessary to 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 in 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	1. Meaningfulness: Measure is evaluated and tailored to unique needs of specific program-target population  2. Appropriateness of scale: measure portfolio is balanced and scaled to meet target program- and population-specific goals, specifically, measure is evaluated in the context of all the measures currently within the program measure portfolio  3. Time-to-value realization: measure has plan for near- and long-term positive impacts on the targeted program and population as measure matures	1. Impact: Measure set evaluated across program, target population, and time 2. Clinician data streams: measure set redundancy in data streams is identified and mitigated, specifically by evaluating the burden associated with reporting the measure, considering other related measures 3. Patient journey: measure set redundancy is identified and mitigated, specifically, by evaluating if the measure addresses the right aspect of care, in the right setting, and at the right point in a in patient's journey to maximize the desired outcome

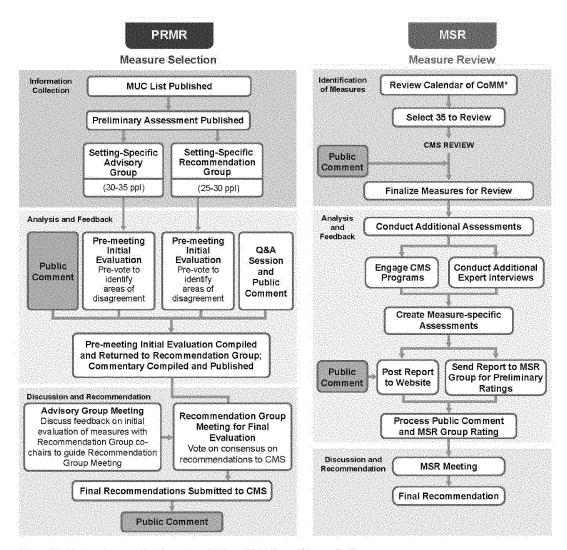


Figure 16. Comparison of Workflows in PRMR and MSR Committee Activities.

#### 4.2 Enhanced PRMR Process

Battelle convened PRMR/MSR committee members, CMS, and other federal partners in Baltimore in April 2024 for the PQM Measure Strategy Summit. The summit aimed to gather feedback on the 2023-2024 PRMR cycle, share the PQM measure strategy and CMS measurement priorities, and obtain input from committees on measure selection for the 2024 MSR cycle.

Based on feedback, Battelle implemented a number of changes to PRMR for the 2024-2025 cycle. The revised <u>Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review (PRMR) and Measure Set Review (MSR)</u>, published in July 2024, reflects these changes. Enhancements focus on refining processes for obtaining committee input, adding clarity to conditions on recommendations, and developing policies for review of instrument-based measures.

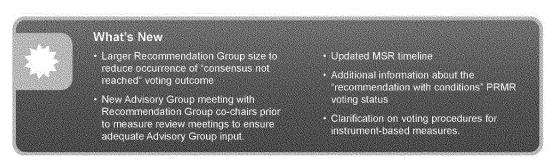
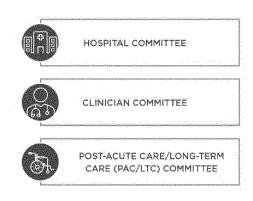


Figure 17. Improvements in PRMR Process For 2024-2025 Cycle.

#### 4.2.1 Obtaining Committee Input

Battelle implemented several steps to enhance the efficiency and effectiveness of committee input. At the 2024 PQM Measure Strategy Summit, Battelle introduced a brief at-a-glance format for sharing summary information on measures with committee members. This summary, called a preliminary assessment, provides information on measure characteristics and potential or realized impact. It was created in response to committee feedback from the 2023-2024 PRMR cycle regarding the volume and complexity of summarized measure information.



Additionally, the committee provided feedback on a shortened pre-meeting evaluation form to capture their initial thoughts on measures under review. Collecting this input in writing helps Battelle meeting facilitators focus the committee recommendation discussion on areas with the greatest disagreement. Together, these revisions ensure that PRMR committee members, including patients, have accessible information about the measures under review and can provide meaningful input into the process.

#### Meaningfulness

 Data describing the evidence of importance, scientific acceptability, feasibility, usability, and use for the target population and entities of the program under consideration

#### Appropriateness of Scale

- Data describing the implementation of the measure for patients/recipients of care addressed by the program
- Data describing the appropriateness of the measure for evaluating measured entities

#### Time to Value Realization

 Data demonstrating the measure will have shortand long-term positive impacts in the targeted program and/or in the targeted population

Like the E&M process, Battelle began using a Novel Hybrid Delphi and Nominal Groups technique<sup>1</sup> for pre-rulemaking measure reviews. Each PRMR committee consists of an Advisory (Delphi) Group and a Recommendation (Nominal) Group, each with specific roles in evaluating and voting on measures. Only Recommendation Group members vote on measures. To ensure meaningful feedback from

Advisory Group members, they meet with their respective Recommendation Group co-chairs to discuss their measure feedback and raise discussion points. This feedback is then carried over to the subsequent Recommendation Group measure review meetings in January 2025. Advisory Group members provide both written feedback and oral comments directly to Recommendation Group co-chairs, strengthening the number of voices contributing to the PRMR process.

Comments received from committee members at the 2024 PQM Measure Strategy Summit highlighted the enhanced PRMR and MSR process's strengths, including transparency, strong facilitation, and collaboration with new groups of interested parties.

## SAMPLE COMMENTS RECEIVED DURING THE 2024 PQM MEASURE STRATEGY SUMMIT

- "Transparency in all processes."
- "Committee discussions."
- "The materials were well organized and shared with PRMR members well in advance."
- "Bringing together a wide range of stakeholders."
- "Collaboration with measure developers, clinical practitioners, and patients."
- "Timely and relevant communication."
- "An enormous number of measures were reviewed, efficient process."
- "Multiple perspectives and collaboration."
- "Well-organized good patient and clinician input."
- "Very well organized and led to meaningful results."
- "Collaborative mutual learning opportunities as well as constructive discussions."
- "Diverse voices/input. Not automatically accepting measures just because."

<sup>1</sup> 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 Services Research. 2011 Dec;46(6pt1):2005-18. https://onlinelibrary.wiley.com/doi/abs/10.1111/ j.1475-6773.2011.01297.x

#### 4.2.2 Maximizing Voting Outcomes

Following committee evaluations, discussions, and votes, CMS receives one of three recommendations for each measure:

- · Recommend: The committee recommends CMS add the measure to the specified program as presented.
- Recommend with conditions: The committee recommends CMS add the measure to the specified program with the consideration of conditions such as additional testing or submission for endorsement by a CBE.
- Do not recommend: The committee does not recommend CMS add the measure into the specified program.

To reach a consensus recommendation, at least 75% of the voting committee members must agree on one of the three options. If this threshold is not met, consensus is not reached. In the 2023-2024 cycle, the PRMR committee reached this voting outcome for 20 of 52 measures.

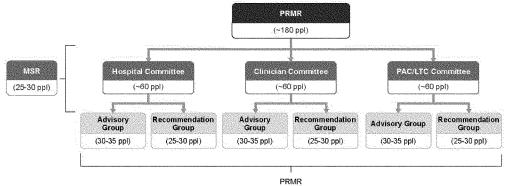
To ensure CMS receives meaningful recommendations alongside qualitative information from the committees, Battelle expanded the Recommendation Group size within each committee from 18-20 to 25-30 members. This increase enhances the likelihood of achieving consensus while maintaining the 75% threshold for defining consensus.

Recommendation Group members expressed confusion about what constitutes a condition that would lead them to fully recommend a measure. In response, additional details were added to the 2024 Guidebook, providing examples of shorter-term (e.g., stratified reporting) and longer-term conditions (e.g., respecifying the numerator). It clarifies that Recommendation

Group members do not need to agree on conditions. Instead, each member who votes to recommend with conditions is asked to supply, orally or in writing, the relevant condition(s) they believe should precede the measure's implementation in a CMS program. These conditions are shared with CMS for consideration in the PRMR Recommendations Report.

Together, the larger Recommendation Group size and clarity around conditions for recommendation strengthen the voting outcomes from the PRMR process.

As seen in Figure 18, each 2024-2025 PRMR committee has approximately 60 members. Each committee is comprised of patients, clinicians, facilities, purchasers, population health experts, researchers, and other interested parties.



- Advisory and Recommendation Groups provide written feedback
- Recommendation Groups meet to review and recommend

Figure 18. 2024-2025 PRMR Committee Structure

#### 4.2.3 Public Engagement

During the 2023-2024 PRMR cycle, the public had two types of opportunities to comment on MUC List measures:

- Written comments: The public could provide written comments from December 1 to December 22. All comments were published on the public PQM website.
- Verbal comments: Battelle facilitated listening sessions for spoken comments, allowing the public and committee members to ask CMS questions about specific measures on the MUC List.

Additionally, after final recommendations were made, the public could submit written comments for CMS's further consideration.

These post-recommendation comments did not influence the final recommendations but provided additional feedback on the measures.

#### 4.3 PRMR Engagement

After posting the final recommendations on MUC List measures for the 2023-2024 PRMR Cycle in February 2024, 161 written public comments were received via the PQM website. These comments offered CMS further insights into the measures under consideration.

For the 2024-2025 cycle, Battelle has completed two rounds of public comment related to the 2024 MUC List:

- A written public comment period from November 25 through December 30, receiving 239 comments from 92 professional organizations, academic institutions, foundations, and patients/patient representatives.
- Three setting-specific listening sessions for spoken public comments, with robust attendance: 270 attendees (Hospital session), 211 attendees (Clinician session), and 104 attendees (PAC/LTC session). During these sessions, 51 attendees voiced comments or questions, engaging with CMS and PQM leadership.

#### 4.4 Annual PRMR Results from the 2023 Measures Under Consideration

In 2023, 42 measures were published on the MUC List. Of these:

- 19 measures were assigned to the Clinician Committee
- 22 measures were assigned to the Hospital Committee
- 3 measures were assigned to the Post-Acute Care/Long-Term Care (PAC/LTC) Committee.
- 2 measures, MUC 199 and MUC 210, were proposed for programs under both Clinician and Hospital committees.

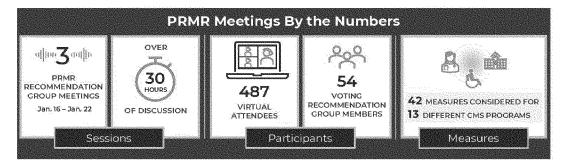


Figure 19, 2023-2024 PRMR Meetings by the Numbers

The PRMR process involves a series of meetings and communications to achieve consensus recommendations for CMS quality reporting and value-based programs. Key elements include:

Public Engagement: A 21-day call for public comment was held via the PQM website, allowing stakeholders to provide written feedback on the measures under consideration. In parallel, a series of setting-specific listening sessions were conducted virtually over Zoom. These sessions provided an opportunity for verbal comments and questions from the public and committee members, facilitating direct engagement with CMS, Battelle and PQM committee members.

#### Preliminary Measure Assessment:

Battelle staff conducted a preliminary assessment (PA) for each measure to provide committee members with a standardized baseline evaluation, facilitating efficient review.

Committee Evaluation: Advisory and Recommendation Group members reviewed the PAs and participated in Round 1 Evaluations to assess initial strengths and areas of concern and generate a starting point for discussion during the Recommendation Group meetings.

#### **Recommendation Group**

**Discussion:** Over three meetings spanning five days, Recommendation Group members from the Clinician, Hospital, and PAC/LTC committees, along with CMS leadership and measure developers, evaluated 42 measures for 13 CMS programs.

**PRMR Votes and Outcomes:** Table 7 outlines the final votes of the Recommendation Group for each CMS program.

Table 7. PRMR Recommendations for 2023 Measures Under Consideration by Program

Program	MUC ID	Measure Title	Recommendation	Conditions (if specified)
Ambulatory Surgical Center Quality Reporting	MUC2023-156	Screening for Social Drivers of Health (SDOH)	Recommend with conditions	The committee did not provide program specific conditions.
Program (ASCGR)	MUC2023-171	Screen Positive Rate for Social Drivers of Health (SDOH)	Consensus not reached	N/A
	MUC2023-175	Facility Commitment to Health Equity	Recommend	N/A
End-Stage Renal Disease Quality Incentive Program (ESRD QIP)	MUC2023-138	ESRD Dialysis Patient Life Goals Survey (PaLS)	Consensus not reached	N/A
Hospice Quality Reporting Program (HQRP)	MUC2023-163	Timely Reassessment of Pain Impact	Recommend with conditions	Conditions included further testing of the Hospice Outcomes and Patient Evaluation (HOPE) tool as well as endorsement of the measure by a consensus-based entity.
	MUC2023-166	Timely Reassessment of Non-Pain Symptom Impact	Recommend with conditions	Conditions included further testing of the HOPE tool as well as endorsement of the measure by a consensus-based entity.
	MUC2023-183, 191, 192	CAHPS® Hospice Survey [Consumer Assessment of Health care Providers and Systems]	Consensus not reached	N/A
	MUC2023-048	Hospital Harm - Falls with injury	Recommend with conditions	Conditions included the measure obtaining consensus-based entity endorsement and ongoing monitoring of unintended consequences such as use of patient restraints and avoidance of life-saving procedures with higher risk for respiratory failure.
Hospital Inpatient Guality Reporting Program (Hospital IQR Program)	MUC2023-049	Thirty-day Risk- Standardized Death Rate among Surgical Inpatients with Complications (Failure- to-Rescue)	Recommend Conditions included the me- with conditions undergoing consensus-base endorsement and the collec- of data to evaluate possible	

Table 7. PRMR Recommendations for 2023 Measures Under Consideration by Program (continued)

Program	MUC ID	Measure Title	Recommendation	Conditions (if specified)
Hospital Inpatient Quality Reporting Program (Hospital IGR Program) (cont.)	MUC2023-050	Hospital Harm - Postoperative Respiratory Failure	Recommend with conditions	Conditions included the measure undergoing consensus-based entity endorsement and ongoing monitoring of unintended consequences such as use of patient restraints and avoidance of life-saving procedures with higher risk for respiratory failure.
	MUC2Ö23-114	Global Malnutrition Composite Score	Recommend with conditions	Conditions included adding hospital-acquired malnutrition and high-risk nutritional practices in screening and assessment and the involvement of more patient groups in further work on this measure.
	MUC2023-139	Hospital Equity Index (HEI)	Consensus not reached	N/A
	MUC2023-146, 147, 148, 149	Hospital Patient Experience of Care	Recommend with conditions	Conditions included endorsement by a consensus-based entity, consideration to not extend survey length and remove overlapping items as the measures progress in the program, the use of adaptive questions in computerized administration to minimize items, and the use of a mechanism to monitor trends in performance data over time.
	MUC2023-188	Patient Safety Structural Measure	Recommend with conditions	Conditions included publication of an implementation guide that clearly documents how safety is measured and using data to narrow the scope before approving the measure for programs.
	MUC2023-196	Age-Friendly Hospital Measure	Consensus not reached	м/А
	MUC2023-199	Connection to Community Service Provider	Consensus not reached	N/A
	MUC2023-210	Resolution of At Least 1 Health-Related Social Need	Consensus not reached	N/A
	MUC2023-219	Central Line-Associated Bloodstream Infection (CLABSI) (Stratified for oncology locations)	Recommend with conditions	Conditions included encouraging CMS to evaluate data by oncology unit type and increase reporting time to allow lower-patient-volume facilities to report.

Table 7. PRMR Recommendations for 2023 Measures Under Consideration by Program (continued)

Program MUC ID Measure Title Recommendation Conditions (if spe		Conditions (if specified)	
MUC2023-220	Catheter-Associated Urinary Tract Infection (CAUTI) (Stratified for oncology locations)	Recommend with conditions	Conditions included encouraging CMS to evaluate data by oncology unit type and increase reporting time to allow lower-patient-volume facilities to report.
MUC2023-156	Screening for Social Drivers of Health (SDOH)	Recommend with conditions	Conditions included that IQR and OQR programs report one set of measures per calendar year per facility.
MUC2023-171	Screen Positive Rate for Social Drivers of Health (SDOH)	Consensus not reached	N/A
MUC2023-172	Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome- Based Performance Measure (Information Transfer PRO-PM)	Recommend with conditions	Conditions included specifying that the survey be administered at the time of the procedure so as not to conflict with collection of pain and function outcome measures.
MUC2023-176	Hospital Commitment to Health Equity	Recommend with conditions	Conditions included the measure undergoing consensus-based entity endorsement, added instructions and information around attestation requirements, and ongoing data collection for further measure testing in low-patient-volume settings.
MUC2023-117	Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)	Consensus not reached	Conditions included encouraging CMS to consider monitoring for unintended consequences and further testing related to health equity.
MUC2023-119	Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure (HF)	Recommend with conditions	Conditions included exploring monitoring for unintended consequences and conducting further testing related to health equity.
MUC2023-120	Excess Days in Acute Care (EDAC) after Hospitalization for Pneumonia (PN)	Recommend with conditions	Conditions included encouraging CMS to consider conditions such as monitoring for unintended consequences and further testing related to health equity.
	MUC2023-156  MUC2023-171  MUC2023-172  MUC2023-176  MUC2023-117	MUC2023-120 Catheter-Associated Urinary Tract Infection (CAUTI) (Stratified for oncology locations)  MUC2023-156 Screening for Social Drivers of Health (SDOH)  MUC2023-171 Screen Positive Rate for Social Drivers of Health (SDOH)  MUC2023-172 Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM)  MUC2023-176 Hospital Commitment to Health Equity  MUC2023-117 Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)  MUC2023-119 Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure (HF)  MUC2023-120 Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure (HF)	MUC2023-120 Catheter-Associated Urinary Tract Infection (CAUTI) (Stratified for oncology locations)  MUC2023-156 Screening for Social Drivers of Health (SDOH)  MUC2023-171 Screen Positive Rate for Social Drivers of Health (SDOH)  MUC2023-172 Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM)  MUC2023-176 Hospital Commitment to Health Equity  MUC2023-177 Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI)  MUC2023-19 Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure (HF)  MUC2023-120 Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure (HF)  MUC2023-120 Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure (HF)  MUC2023-120 Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure (HF)  MUC2023-120 Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure (HF)

Table 7. PRMR Recommendations for 2023 Measures Under Consideration by Program (continued)

Program MUC ID Measure		Measure Title	Recommendation	Conditions (if specified)
Hospital Value- Based Purchasing Program (HVBP)	MUC2023-146, 147, 148, 149	Hospital Patient Experience of Care	Recommend with conditions	Conditions included endorsement by a consensus-based entity, consideration to not extend survey length and remove overlapping items as the measures progress in the program, the use of adaptive questions in computerized administration to minimize items, and the use of a mechanism to monitor trends in performance data over time.
Inpatient Psychiatric Facility Guality Reporting Program (IPFGR)	MUC2023-181	30-Day Risk- Standardized All-Cause Emergency Department Visit Following an Inpatient Psychiatric Facility Discharge (IPF ED Visit measure)	Recommend with conditions	Conditions included endorsement by a consensus-based entity.
Medicare Promoting Interoperability Program for Eligible Hospitals (EHs) or Critical Access Hospitals (CAHs)(PI)	MUC2023-048	Hospital Harm - Falls with Injury	Recommend with conditions	Conditions included the measure undergoing consensus-based entity endorsement and ongoing monitoring of unintended consequences such as use of patient restraints and avoidance of life-saving procedures with higher risk for respiratory failure.
	MUC2023-050	Hospital Harm - Postoperative Respiratory Failure	Recommend with conditions	Conditions included the measure undergoing consensus-based entity endorsement and ongoing monitoring of unintended consequences such as use of patient restraints and avoidance of life-saving procedures with higher risk for respiratory failure.
	MUC2023-114	Global Malnutrition Composite Score	Recommend with conditions	Conditions included adding hospital-acquired malnutrition and high-risk nutritional practices in screening and assessment and the involvement of more patient groups in further work on this measure.
Merit-based Incentive Payment System (MIPS)	MUC2023-141	Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy	Recommend with conditions	Conditions included additional testing to examine measure performance and feasibility.
	MUC2023-161	Appropriate Germline Testing for Ovarian Cancer Patients	Recommend with conditions	Conditions included endorsement by a consensus-based entity.

Table 7. PRMR Recommendations for 2023 Measures Under Consideration by Program (continued)

Program	MUC ID	Measure Title Recommendation		Conditions (if specified)
Merit-based Incentive Payment System (MIPS) (cont.)	MUC2023-162	Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer	Recommend with conditions	Conditions included encouraging CMS to consider implementation at the clinician group level only until further testing and improvements can be made at the individual clinician level.
	MUC2023-164	Adult COVID-19 Vaccination Status	Consensus not reached	N/A
	MUC2023-190	Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer	Consensus not reached	N/A
	MUC2023-201	Cataract Removal with Intraocular Lens (IOL) Implantation	Recommend with conditions	While the committee did not provide a formal list of conditions, they advocated more examination of how implementation of cost measures may impact patient outcomes.
	MUC2023-203	Chronic Kidney Disease	Consensus not reached	N/A
	MUC2023-204	End-Stage Renal Disease	Consensus not reached	N/A
	MUC2023-205	Inpatient (IP) Percutaneous Coronary Intervention (PCI)	Recommend with conditions	Conditions included the measure undergoing consensus-based entity endorsement to assess the scientific properties of the measure with rigor. Analyze longitudinal data to assess the stability of the measure.
	MUC2023-206	Kidney Transplant Management	Consensus not reached	N/A
	MUC2023-207	Prostate Cancer	Consensus not reached	N/A
	MUC2023-208	Respiratory Infection Hospitalization	Consensus not reached	N/A
	MUC2023-209	Rheumatoid Arthritis	Do not recommend	N/A
	MUC2023-211	Melanoma: Tracking and Evaluation of Recurrence	Consensus not reached	N/A

Table 7. PRMR Recommendations for 2023 Measures Under Consideration by Program (continued)

Program MUC ID Measure Title Recommendation Conditions (if s		Conditions (if specified)		
Part C & D Star Ratings (Part C and D)	MUG2023-137	Initial Opioid Prescribing for Long Duration (IOP-LD)	Consensus not reached	N/A
	MUC2023-179	Initiation and Engagement of Substance Use Disorder Treatment (IET)	Consensus not reached	N/A
	MUC2023-212	Level I Denials Upheld Rate Measure	Recommend	N/A
Prospective MUC2023-146, Hospital Patient Recommend Payment System- Exempt Cancer Hospital Quality Reporting Program (PCHQRP)  MUC2023-146, Hospital Patient Recommend with condition		Recommend with conditions	Conditions included endorsement by a consensus-based entity, consideration to not extend survey length and remove overlapping items as the measures progress in the program, the use of adaptive questions in computerized administration to minimize items, and the use of a mechanism to monitor trends in performance data over time.	
	MUC2023-188	Patient Safety Structural Measure	Recommend with conditions	The committee encouraged publication of an implementation guide that clearly documents how safety is to be measured and using data to narrow the scope before approving the measure for programs.
Rural Emergency Hospital Quality Reporting Program	MUC2023-156	Screening for Social Drivers of Health (SDOH)	Recommend with conditions	Conditions included that IQR and OQR programs report one set of measures per calendar year per facility.
(REHQRP)	MUC2023-171	Screen Positive Rate for Social Drivers of Health (SDOH)	Consensus not reached	N/A
	MUC2023-176.	Hospital Commitment to Health Equity	Recommend with conditions	Conditions included the measure undergoing consensus-based entity endorsement, added instructions and information around attestation requirements, and ongoing data collection for further measure testing in low-patient-volume settings.

#### 4.5 PRMR Gaps Identified

During the PRMR meetings in January 2024, Recommendation Group members identified several recurring themes for improving measures and measure sets. These themes highlight areas where members would like to see measure developers and CMS focus their resources in future CMS programs during pre-rulemaking.

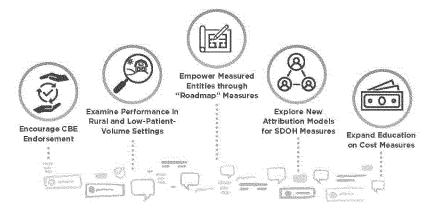


Figure 20. Growth Opportunities for CMS Programs



#### **Encourage CBE Endorsement**

**Consideration:** CMS should consider emphasizing the importance of CBE (Consensus-Based Entity) endorsement to promote effective program discussions and ensure measures meet high scientific standards.

During the PRMR meetings in January 2024, a recurring theme was the committee's uncertainty about measure performance and scientific acceptability based on the information submitted to the CMS Measures under Consideration Entry and Review Tool (MERIT). The most common condition for recommending measures was that they undergo CBE endorsement. CBE endorsement is valued for ensuring scientific rigor, as endorsement committees, with their subject matter expertise in measurement science, are better suited to evaluate concerns such as reliability and validity. Currently, measures under consideration are not required to have CBE endorsement before being submitted for CMS program consideration. Emphasizing CBE endorsement could enhance the quality and reliability of CMS programs.



#### **Examine Performance in Rural and Low-Patient-Volume Settings**

**Consideration:** CMS and measure developers are encouraged to explore the unique implementation considerations needed for successful measure use in rural areas and low-patient-volume settings.

During the PRMR sessions, interested parties representing rural communities urged committees to consider how measure implementation and performance might vary across different settings. Committee members examined measure specifications and discussed examples of how certain measures could have unintended consequences or lower performance in facilities with low patient volumes. Continuing the emphasis on engaging rural perspectives, discussed during the Fall 2023 Measure Set Review, CMS and measure developers are encouraged to include rural and/or low-patient-volume testing sites in future measure development. Discussions highlighted that low patient volume is often due to a facility serving a rural area, but other socioeconomic factors may also contribute to low patient volumes, which should be considered during measure specification and testing. CMS is further encouraged to explore implementation guides and supports for rural and low-patient-volume settings to address barriers to implementation and performance variation resulting from measures historically not considering the unique needs of these settings.



#### **Empower Measured Entities through "Roadmap" Measures**

**Consideration:** CMS and measure developers are encouraged to explore new models for attribution of performance that better reflect the multi-provider and community-level work being undertaken to address Social Determinants of Health (SDOH).

In discussions about measures on the 2023 MUC List, committee members acknowledged the importance of measure intent but noted barriers to implementation, such as lack of institutional support and limited flexibility. The MUC2023-196 Age-Friendly Hospital measure was highlighted for its broadly defined domains, which allow some flexibility at the facility level. This measure was seen as a potential "roadmap" for hospitals to become age-friendly while measuring progress. Hallmarks of a roadmap measure may include offering flexibility in achieving high performance within each domain, using attribution models that reflect real-world care delivery and external risk factors, and framing these measures as tools to empower entities to expand work in new areas to better serve communities.



#### Explore New Attribution Models for Social Determinants of Health Measures

**Consideration:** CMS and measure developers are encouraged to explore new models for attribution of performance that better reflect the multi-provider and community-level work being undertaken to address Social Determinants of Health (SDOH).

The 2023 MUC List included several measures that expanded measurement into the area of SDOH in meaningful ways. PRMR committees supported the intent of these measures and recognized the impact of SDOH on outcomes from the patient, clinician, and facility perspectives. However, committees struggled to reach consensus on recommendations for most of these measures. A common concern was the attribution level, as committee members frequently noted that clinicians and hospitals are not solely responsible for addressing SDOH concerns. In the absence of a robust community service provider system, they may face undue challenges in implementing these measures or have publicly reported poor performance. Exploring new attribution models could better capture the collaborative efforts required to address SDOH effectively.



#### **Expand Education on Cost Measures**

**Consideration:** CMS is encouraged to expand education for measured entities on the "why" and "how" of cost measures to enhance understanding and utility, particularly in the context of MIPS.

During the Clinician Committee's robust question-and-answer session with CMS and developers regarding cost measures proposed for MIPS, committee members expressed concerns and asked fundamental questions about the impact of cost measures on quality of care and patient outcomes. They also questioned the utility of cost measures for clinicians in improving their processes over time. While CMS program leads and measure scientists discussed the role and statutory requirement for cost measures in programs such as MIPS, there is room for broader discussion and education around cost measures. Interested parties encourage CMS to expand education for those most impacted by cost measures to better understand them. Additionally, PQM will explore ways to improve committee members' understanding of cost measures as part of the next PRMR cycle to ensure robust and measure-relevant discussions.

# 5.0 Multi-Stakeholder Engagement: Measure Set Review (MSR)

The MSR process is statutorily enabled by the <u>Consolidated Appropriations Act. 2021</u>, Public Law 116–260, which reads: "Section 1890(b) of the Social Security Act (42 U.S.C. 1395aaa(b)) is amended by inserting after paragraph (3) the following new paragraph: "(4) REMOVAL OF MEASURES.—The entity may provide input to the Secretary on quality and efficiency measures described in paragraph (7) (B) that could be considered for removal."

In 2024, the MSR Committee reviewed 35 Cost Effectiveness and Efficiency in Health Care Utilization measures from ten Centers for Medicare & Medicaid Services (CMS) programs and recommended six (6) for removal.

#### 5.1 MSR Overview

The Measure Set Review (MSR) process is designed to optimize the CMS measure portfolio by recommending measures for removal based on updated information about their properties, performance trends, and alignment with program needs and priorities. The MSR process evaluates measures through three key domains:

 Meaningfulness: The measure meets criteria for importance, feasibility, scientific acceptability, and usability and use, considering its use across programs and populations.

- Data Stream Parsimony: Measure redundancy in data streams has been identified and mitigated.
- Patient Journey: The measure is implemented across the patient journey as intended per a measure impact model, using a measure impact model to illustrate how the measure can have the greatest impact on patient outcomes.

These domains help ensure that the measures retained in the CMS portfolio are effective, efficient, and aligned with the overarching goals of improving health care quality and outcomes.



Figure 21. MSR Timeline

5.0 Multi-Stakeholder Engagement: Measure Set Review (MSR) | 50

#### 5.2 Enhanced MSR Process

The <u>Guidebook of Policies and Procedures for PRMR and MSR</u>, published in July 2024, introduced several enhancements to the MSR process:

- Use of CMS Quality Strategy: The Cascade of Meaningful Measures was utilized to select measure priority areas, such as patient safety, for review.
- Public Comment Opportunities: Additional and earlier opportunities for public comment were provided to gather more comprehensive feedback.
- Preliminary Assessments: Battelle staff were assigned to prepare preliminary assessments using review methods aligned with E&M and PRMR to inform committee reviews.

These enhancements aimed to achieve more effective committee reviews by providing more information from public comments and staff assessments, ultimately optimizing the CMS measure portfolio.

#### **5.3 MSR Committee**

Battelle staff conducted a public call for nominations and targeted outreach to solicit nominees for the PRMR committees. For the MSR Recommendation Group, there is no separate nominations process; instead, Battelle annually selects members who are currently serving on PRMR committees to serve a 1-year term on the MSR Recommendation Group. The goal was to create a balanced Recommendation Group that brings variations in experience, expertise, and perspectives. To facilitate the meeting, Battelle solicited one patient co-chair and one facility association co-chair. This approach ensures balanced representation and effective facilitation in the review process.

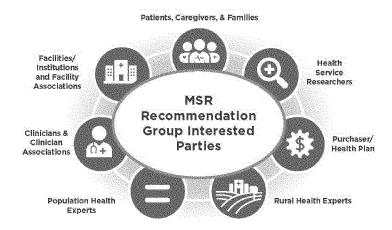


Figure 22. MSR Recommendation Group Interested Parties

#### 5.4 2024 MSR Measure Selection

At the launch of the 2024 MSR cycle, Battelle staff conducted a detailed review of 107 measures in the CMS Measures Inventory Tool (CMIT) that were categorized under the primary priority of Affordability and Efficiency within the Cascade of Meaningful Measures. Here's a summary of the process:

#### REVIEW AND PRIORITIZATION:

- Initial Review: 107 measures were reviewed by Battelle staff.
- Prioritization: 34 measures were prioritized for potential MSR review based on input from the 2024 PQM Measure Strategy Summit.
  - » Nine Measures: Selected due to questions about actionability and alignment with clinical guidelines.
  - » 25 Measures: Chosen for their potential impact, actionability, and possible redundancy with other measures.

#### CONSIDERATIONS FOR PRIORITIZATION:

- Actionability: Measures with unclear paths to improvement or multiple influencing factors.
- Clinical Guidelines: Measures monitoring well-established guidelines to assess ongoing impact and reasons for noncompliance.
  - » Potential Impact: Measures with defined improvement paths but still needing clarity.
  - » Redundancy: Measures with similar focuses across programs, especially in emergency department utilization and readmission, for potential alignment or reduction.

#### **PUBLIC COMMENT PERIODS:**

- · First Comment Period (May 15-31, 2024):
  - » Draft list of 34 measures was posted for public comment.
  - » Received 27 comments, mostly expressing support or concern for specific measures.
  - » Comments were summarized for the MSR Recommendation Group meeting.
- Second Comment Period (Prior to September 30, 2024):
  - » Preliminary assessment reports were published for a 21-day public comment period.
  - » Feedback from both comment periods was summarized and presented during the MSR Recommendation Meeting.

#### **FINAL SELECTION**

 Review and Select: Battelle further refined the MSR with CMS input on rulemaking considerations, resulting in the full set of 35 measures across 10 CMS programs.



Figure 23. Measure Set Review Meeting Attendance

#### 5.5 2024 MSR Measure Review Results

On September 30 – October 1, 2024, MSR members met to discuss the 35 selected measures. Following a review of each measure and a vote, six (6) measures were recommended for removal and 29 measures were recommended for continued use.

Table 8 outlines the final vote counts and recommendations for the 2024 measure set.

Table 8. MSR Recommendation Group Vote Counts\* per Measure

CMITID	MEASURE TITLE	RETAIN	REMOVE	RECUSALS
:00033-01-C-M(PS:	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	<b>23</b> (100%)	0 (0%)	°O.
00039-01-C-MIPS	Age Appropriate Screening Colonoscopy	7 <sup>(</sup> (30%)	16 (70%)	
00076-02-E-MIPS	O076-02-E-MIPS  Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture		16 (67%)	0
.00487-01-C-MIPS	Overuse of Imaging for the Evaluation of Primary Headache	18 (75%)	6 (25%)	1:
00101-01-C-MIPS	Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients	5 (21%)	19 (79%)	Q,
00069-01-C-MIPS	Appropriate Follow-up Imaging for Incidental Abdominal Lesions	22 (92%)	2 (8%)	1
00070-01-C-MIPS	Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients	23 (96%)	1 (4%)	1:
00419-01-C-MIPS	Maternity Care: Elective Delivery (Without Medical Indication) at less than 39 Weeks (Overuse)	18 (75%)	6 (25%)	
00237-02-C-MIPS	Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years	23 (100%)	0 (0%)	· Q.

Table 8. MSR Recommendation Group Vote Counts\* per Measure (Continued)

CMITID	MEASURE TITLE	RETAIN	REMOVE	RECUSALS
00237-01-C-MIPS	Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older		0 (0%)	Ö
00543-01-C-MIPS	Percentage of Patients Who Died from Cancer Receiving Systemic Cancer- Directed Therapy in the Last 14 Days of Life (lower score - better)	23 (100%)	0 (0%)	0
00737-01-C-MIPS	Unplanned Reoperation within the 30- Day Postoperative Period	21 (95%)	1 (5%)	· O
00736-01-C-MIPS	Unplanned Hospital Readmission within 30 Days of Principal Procedure	9 (39%)	14 (61%)	0
00561-02-C-PARTC	Plan All-Cause Readmissions	18 (78%)	5 (22%)	Ö
00452-01-C-PARTD	MPF Price Accuracy	23 (100%)	O (0%)	0
00005-01-C-HOQR	Abdomen Computed Tomography (CT) - Use of Contrast Material	14 (64%)	8 (36%)	1
00097-01-C-HOQR	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery	0.	22 (100%)	1
00453-01-C-HOQR	MRI Lumbar Spine for Low Back Pain	1 (4%)	22 (96%)	1
00021-02-C-HOQR	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	16 (73%)	6 (27%)	0
00021-01-C-PCHQR	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	17 (77%)	5 (23%)	0
00004-01-C-PCHQR	30-Day Unplanned Readmissions for Cancer Patients	20 (91%)	2 (9%)	O <sub>j</sub>

Table 8. MSR Recommendation Group Vote Counts\* per Measure (Continued)

CMIT ID	MEASURE TITLE	RETAIN	REMOVE	RECUSALS
00045-01-C-ASCQR	.All-Cause Hospital Transfer/Admission	22 (96%)	1 (4%)	0
00253-01-C-HOQR	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	20 (87%)	3 (13%)	Ö
00253-01-C-ASCQR	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	19 (86%)	3 (14%)	Ö
00345-02-C-ASCQR	Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures	22 (96%)	1 (4%)	0
00346-02-C-ASCQR	Hospital Visits After Urology Ambulatory Surgical Center Procedures	21 (100%)	,0 (0%)	Ô
00254-01-C-ASCQR	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers	20 (100%)	O (0%)	Ö
00576-01-C-IRFQR	Potentially Preventable Within Stay Readmission Measure for Inpatient Rehabilitation Facility Quality Reporting Program	20 (91%)	2 (9%)	O
00210-05-C-HHQR	Discharge to Community (DTC) - Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP)	21 (95%)	1 (5%)	
00210-03-C-LTCHQR	Discharge to Community (DTC) - Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)	20 (100%)	O (0%)	Ö
00210-02-C-SNFQRP	Discharge to Community (DTC) - Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)	21 (100%)	(0%)	9
00575-04-C-HHQR	Potentially Preventable 30-Day Post- Discharge Readmission Measure for HH Quality Reporting Program	16 (80%)	4 (20%)	Ö

Table 8. MSR Recommendation Group Vote Counts\* per Measure (Continued)

CMIT ID	MEASURE TITLE	RETAIN	REMOVE	RECUSALS
00575-01-C-IRFQR	Potentially Preventable 30-Day Post- Discharge Readmission Measure for Inpatient Rehabilitation Facility Quality Reporting Program	17 (85%)	3 (15%)	0
00575-02-C-LTCHQR	Potentially Preventable 30-Day Post- Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)	17 (85%)	3 (15%)	0
00575-03-C-SNFQRP	Potentially Preventable 30-Day Post- Discharge Readmission Measure for Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)	17 (85%)	3 (15%)	O:

<sup>\*</sup>During the 2-day MSR Recommendation Group meeting, the total members voting varied as some members had to attend to professional duties but discussion and voting quorum was maintained for all measures. This fluctuation in total voting members is reflected in the vote counts in this table.

There is a growing interest among committee members in understanding how SDOH might affect the implementation and performance of various measures across different populations. SDOH are environmental conditions that exist where people live, work, and receive medical care that influence health outcomes and risks.<sup>2</sup> These include factors like economic stability, education access and quality, health care access and quality, neighborhood and built environment, and the social and community context.

Healthy People 2030, U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. Retrieved from https://health.gov/healthypeople/objectives-and-data/social-determinants-health

# **6.0 Core Quality Measures Collaborative** (CQMC)

The CQMC (Core Quality Measures Collaborative) is a coalition of health care leaders focused on aligning measures across payers to improve health care quality in the United States. Founded in 2015 as a public-private partnership between AHIP and CMS, the CQMC includes over 70 organizations, such as health insurance companies, medical societies, consumer and employer groups, and quality collaboratives. Battelle, in its role as the CBE, convenes the CQMC.

#### **Key Objectives of CQMC:**

- Identify High-Value
   Measures: Focus on evidence-based measures that
   promote better health outcomes and provide useful
   information for improvement, decision-making, and
   payment.
- Align Measures Across
   Payers: Achieve congruence in the use of measures for quality improvement, transparency, and payment purposes.
- Reduce Measurement Burden: Eliminate low-value metrics, redundancies, and inconsistencies in measure specifications and reporting requirements.

#### Core Measure Sets:

The CQMC maintains and updates core measure sets to reflect changes in clinical practice guidelines, data sources, and risk adjustment. As of December 2024, the core measure sets include:

- Accountable Care Organizations/ Patient-Centered Medical Homes/ Primary Care
- Behavioral Health\*
- Cardiology
- Gastroenterology
- HIV & Hepatitis C
- Medical Oncology
- · Neurology
- Obstetrics & Gynecology\*
- · Orthopedics
- · Pediatrics

(\*indicates measure sets updated in August 2024; five additional sets updated but not yet announced.)

#### 2024 Strategic Meeting:

In October 2024, Battelle convened the CQMC Full Annual Strategic Meeting to review progress and set priorities.

The CQMC also discussed barriers to adopting measures within the core sets and strategies to overcome these challenges, aiming to develop a vision and strategy for future work phases.

### 7.0 Ad Hoc Projects

Battelle is developing a CBE Quality Measurement Strategy to guide the evolution of quality measurement science over the next five years. This strategy is supported by work on four ad hoc projects:

- Artificial Intelligence Pilot (AI Pilot): Exploring the integration of AI to enhance quality measurement processes.
- Digital-Readiness Assessment: Evaluating the current state of digital capabilities to support quality measurement.
- CBE Portfolio Gap Analysis: Identifying gaps in the current portfolio to ensure comprehensive coverage of quality measures.
- Refinement of the 5-Year Strategy: Continuously updating the strategy to reflect advancements and changes in the field.

These efforts aim to advance quality measurement science by incorporating innovative technologies and addressing existing gaps.

#### 7.1 Al Pilot

The AI Pilot aims to assess the usefulness of AI technologies in supporting clinical quality measure (CQM) evidence reviews under the E&M process and the PRMR process. The goal is to ensure trustworthy CQMs for use in accountability programs, with AI supporting trustworthiness in two key respects:

#### 1. Explicit Evaluation of Evidence:

- » Al can make all evidence explicit and evaluate it explicitly.
- » An "AI Agent" can use natural language processing to identify relevant published literature and large language models (LLMs) to assess the support and quality of the evidence.
- » The AI Agent can produce arguments about whether the evidence is established or speculative and whether the measure is likely to be endorsed.

#### 2. Guarding Against Confirmation Bias:

- » Al can help prevent the unintended tendency to process information consistent with existing beliefs.
- » Using a carefully constructed "ontology," Al can generate additional claims about a measure's properties and search for supporting literature.
- » Every claim is assumed unsubstantiated and must be supported by evidence and arguments, which are transparent and assessed by subject matter experts.

The ultimate goal of the AI Pilot is to reduce the time and burden of CQM evidence reviews for interested parties and measure development for programs.

#### 7.2 Digital-Readiness Assessment

The Digital-Readiness Assessment is part of Battelle's efforts to transition clinical quality measures (CQMs) to digital data sources, motivated by two key HHS policy objectives:

- Reducing Data Collection Burden: By using modern interoperability standards like USCDI [United States Core Data for Interoperability] and FHIR [Fast Healthcare Interoperability Resources], digital measures aim to streamline data capture and exchange, reducing the burden on measured entities.
- Promoting Multi-Payer Alignment: Digital measures use standards-based, computable specifications to calculate measures from a common source, minimizing reliance on payer-specific data streams.

The transition to digital measures involves four domains or work streams:

- 1. Improving Data Quality
- 2. Advancing Technology
- 3. Optimizing Data Aggregation
- 4. Enabling Alignment of Data, Tools, and Measures

## 7.2.1 Enabling Alignment of Data, Tools and Measures

Battelle, as the CBE, has a key role to play in the fourth workstream: enabling alignment of data, tools, and measures. As part of the E&M and PRMR processes, measure developers are beginning to submit measures specified using these modern interoperability standards.

The transition to digital measures is motivated by two policy objectives, which are not mutually exclusive:

#### 1. Providing Technical Expertise:

- » Support committee reviews of digital measure specifications.
- » Increase the proportion of clinical informatics and data science representatives on the Advisory and Recommendation Group committees.
- » Explore the creation of a separate review panel specifically for digital measures.

#### 2. Developing Assessment Criteria:

- » Collaborate with PQM members who have informatics expertise to develop a set of criteria or a checklist.
- » Use these criteria to internally assess digital measures before they are reviewed by committees.

These efforts aim to ensure that digital measures are effectively evaluated and aligned with modern interoperability standards, facilitating a smoother transition and implementation process.

#### 7.2.2 Digital-Readiness Assessment

The transition to digital measures is driven by two main policy objectives:

#### 1. Providing Technical Expertise:

- » We aim to support committee reviews of digital measure specifications by increasing the representation of clinical informatics and data science experts on the Advisory and Recommendation Group committees.
- » We are exploring the creation of a separate review panel specifically for digital measures to ensure thorough evaluation.
- » Our collaboration with PQM members who have informatics expertise will help us develop a set of criteria or a checklist. This will guide Battelle staff in internally assessing digital measures before they are reviewed by committees.

#### 2. Assessing Digital Readiness:

- » We are gathering information on the various categories of burden associated with the collection, reporting, and use of quality data. This will help identify measures that are suitable candidates for digital transition.
- » We will also identify measures that may face significant obstacles due to reliance on data not currently included in interoperability standards.
- » The metrics we develop will quantify the burden-benefit trade-off in quality measurement. This will inform which measures should be prioritized for digital transition and which may be retired or considered for alternative use.

#### 7.2.3 Burden Assessment

Our burden assessment focuses on understanding the challenges and costs associated with current quality measures and the potential benefits of transitioning to digital measures.

#### Johns Hopkins Study<sup>3</sup>:

- » This study revealed that significant resources are spent on quality reporting, with claims-based metrics being unexpectedly resource-intensive due to the time and resources needed to ensure code accuracy.
- » Clinical measures using data collected during routine care were found to have a lower burden, supporting the transition to digital measures.

#### AHRQ EPC Paper<sup>4</sup>:

» Researchers identified 11 categories of documentation burden, including time spent in EHR, clinical documentation, and administrative tasks. » The study highlighted the need for balanced and new perspectives and valid categories to assess interventions aimed at reducing burden.

The focus on the digital-readiness review is to understand the methodology used for these burden estimates and how that methodology maps to the burden categories. The measure burden assessment will provide a relative assessment of entity and/or person burden rather than an exact dollar estimate. Our intent is to compare burden to measure benefit or impact, giving the Advisory and Recommendation Group a general sense of the benefit-burden trade-off in a systematic manner.

#### 7.3 CBE Portfolio Gap Analysis

During the PRMR in-person meeting in April 2024, committee members from Clinician, Hospital, and PAC/LTC clearly defined the focus areas for measure reviews: actionability, impact, burden, and strategy. By "strategy," they referred to the rationale for a measure within the broader CBE and CMS measure portfolios. The CBE Portfolio Gap Analysis aims to systematically assess these portfolios to identify potential redundancies and gaps where new measures might be needed.

#### STEPS IN THE GAP ANALYSIS:

#### Comprehensive Assessment of Current Portfolios:

- » We conducted a thorough assessment of the current measure portfolios using tools like the PQM STAR database, CMS Measures Inventory Tool (CMIT), PubMed, and the Unified Medical Language System (UMLS).
- » We extracted the current version of the CBE and CMS measure inventory, focusing on measures in active status (524 as of December 31, 2024).

<sup>3</sup> Saraswathula A, Merck SJ, Bai G, et al. The Volume and Cost of Quality Metric Reporting. JAMA. 2023;329(21):1840–1847. doi:10.1001/jama.2023.7271

<sup>4</sup> Wang, Z West CP, Vaa Stelling, BE, Hasan B, Simha, S, Saadi, S, Firwana, M, Nayfeh, T, Viola, KE, Prokop, LJ, , Murad, MH. Measuring Documentation Burden in Healthcare. Technical Brief No. 47. (Prepared by the Mayo Clinic Evidence-based Practice Center under Contract No. 75Q80120D00005/75Q80123F32005.) AHRQ Publication No. 24-EHC023. Rockville, MD: Agency for Healthcare Research and Quality. May 2024. DOI: https://doi.org/10.23970/AHRQEPCTB47.

- » Each measure was assessed based on attributes such as program, reporting status, measure type, care setting, CBE status, format (CQM, eCQM), digital status, Universal Foundation status, and Cascade priority.
- » This assessment helped identify gap areas where the measure portfolio could be better balanced.

#### 2. Assessment by Condition:

- » We compared the distribution of target populations in the current inventory against reference standards like the Common Framework, high-impact conditions, and the National Academies' lists of "Vital Signs" and "Core Metrics."
- » We analyzed the number of measures per condition compared to leading causes of mortality and morbidity and the most frequently indexed conditions in PubMed over the last 10 years.
- » This comparison ensured the portfolio addresses emerging conditions, such as gene and cell therapy, and identified gap areas for more impactful measures.

#### 3. Assessment of Measure Importance:

- » We used structure-process-outcome pyramids and the person health care journey to assess measure importance.
- » For each condition, we evaluated the number of structure, process, and outcome measures, identifying gaps where new measures might support assessment.
- » We assessed how the measure portfolio supports the person's health care journey from "home-tohome," assigning each measure to a specific phase of the journey—population, ambulatory, acute, or post-acute.

The gap analysis is ongoing, with additional results to be published over the next year. This systematic approach helps ensure the measure portfolio is comprehensive and aligned with current health care needs.

#### 7.4 CBE 5-Year Strategic Plan

The AI Pilot, Digital-Readiness Assessment, and CBE Portfolio Gap Analysis all contribute to the implementation of the CBE 5-Year Strategic Plan. This plan focuses on reducing the perceived burden of quality measurement by both decreasing the burden and increasing the benefit.

#### **KEY TENETS OF THE 5-YEAR VISION:**

#### 1. Enhancing Agency:

- » We aim to enhance the sense of agency experienced by individuals and measured entities, supporting their sense of control over the quality measurement process.
- » This is achieved by fostering meaningful community engagement and rigorously applying evidence-based principles, a concept we refer to as "pay for transformation."

#### 2. Purposeful Examination of Measures:

- » The CBE program focuses on examining the purpose of each measure, determining what makes it effective, for whom, and under what conditions.
- » By understanding these factors, we can ensure that measures are meaningful and impactful, aligning with the broader goals of quality improvement.

The strategic plan is designed to create a more efficient and effective quality measurement system, ultimately benefiting both the entities involved and the broader health care community.

#### **CBE VISION:**

Leverage the consensus-based entity (CBE) processes to realize health care system change through the intentional integration of quality measurement and quality improvement processes, principles of evidence-based policies and programs, and meaningful community engagement.

Table 9. Five-Year Vision for the Consensus-Based Entity.

PRIORITY	SYSTEM CHANGE	MILESTONES
Α	Quality measurement will be less burdensome.	<ul> <li>Quality measures are based on interoperability standards (USCDI, FHIR).</li> </ul>
		<ul> <li>Data are captured either in the clinical workflow or using artificial intelligence.</li> </ul>
В	Quality measurement will be more beneficial.	Quality measures are focused on domains where quality measurement is the best strategy to improve population health.
		Other explicit strategies are focused on domains where another approach is the best strategy to improve population health.
С	C Quality measurement will work for both entities (e.g., clini-	New mechanisms exist other than public reporting (e.g., quality councils) for meaningful person engagement.
	cians, facilities) and persons (e.g., patients, beneficiaries).	<ul> <li>Evidence generation is embedded in health care delivery and informs structural change for meaningful entity engagement (e.g., rural).</li> </ul>
D	Quality measurement will be community and transformation	"Pay for Transformation" communities take responsibility for quality, safety, access, and cost.
	focused.	<ul> <li>Communities are self-forming and enabled by AI and interoperable data.</li> </ul>
E	Quality measurement will be trustworthy.	Evidence-based policy is built on the foundation of the "assurance case" (claim-argument-evidence).
		<ul> <li>All assurance laboratory ensures quality measure safety and effectiveness.</li> </ul>
F	Developing quality measures will be less expensive.	Battelle will leverage autonomous Al agents to reduce the time and resources required to develop a trustworthy quality measure.

## 8.0 Financial Information for Fiscal Year 2024

Pursuant to §1890(b)(5)(A)(ii)(l) and (II), the CBE must present "an itemization of financial information for the fiscal year ending September 30 of the preceding year, including—(I) annual revenues of the entity (including any government funding, private sector contributions, grants, membership revenues, and investment revenue) and (II) annual expenses of the entity (including grants paid, benefits paid, salaries or other compensation, fundraising expenses, and overhead costs)."

#### 8.1 Battelle Finances

In Fiscal Year (FY) 2024, Battelle reported revenues of approximately \$13.2 billion. These revenues were derived from a combination of federal funds or government revenue authorized under \$1890(d) of the Social Security Act (SSA), private-sector contributions, and investment revenue. Notably, Battelle does not charge participants for PQM membership, reflecting its commitment to fostering collaboration without financial barriers.

On the expense side, Battelle's expenditures for FY 2024 totaled about \$13.1 billion. These expenses encompassed a range of categories, including grants and benefits paid, salaries and other compensations, purchased services such as subcontracting, fundraising expenses, and overhead costs.

Table 10. Battelle's Unaudited Financial Statement of Revenues and Expenses, for FY2024

#### Financial Statement Fiscal Year 2024 (unaudited)

Account Type	Amount (\$)
Government Revenue	13,148,722,233
Commercial Revenue	108,801,622
Other Revenue	6,501,297
Total Revenue	13,264,025,152
Investment Income	118,674,647
Salaries and Benefits	7,584,048,072
Purchased Services and Materials	5,255,099,904
Other Expense	327,619;544
Total Expense	13,166,767,520

#### 8.2 NCDC Finances

Pursuant to \$1890(b)(5)(A)(ii)(III), the CBE must provide "a breakdown of the amount awarded per contracted task order and the specific projects funded in each task order assigned to the entity." Table 11 lists the tasks with award amounts and funded amounts in the base period of the contract.

Table 11. Federally Funded Tasks Awarded and Funded in FY 2024 Under IDIQ Contract 75FCMC23C0010

(SLIN) <sup>a</sup>	Description	Awarded, \$	Funded, \$
CLIN0003			
0002AA	Measures Reviewed: Endorsement and Maintenance	\$3,799,080	\$3,799,080
0002AB	(OPTIONAL) Measures Reviewed: Endorsement and Maintenance	\$611,680	\$0
0002AC	Measures Reviewed: Pre-Rulemaking	\$1,133,160	\$1,133,160
0002AD	(OPTIONAL) Measures Reviewed: Pre-Rulemaking	\$361,485	\$0
0002AE	(OPTIONAL) Measures Reviewed: Pre-Rulemaking	\$361,485	\$0
0002AF	Measures Reviewed: Measure Set Review	\$358,085	\$358,085
0002AG	(OPTIONAL): Measures Reviewed: Measure Set Review	\$155,730	\$0.
0002AH	(Deliverable 2-3) Final Project Management Plan	\$1,039,676	\$1,039,676
0002AJ	(Deliverable 2-13) Final Annual Report	\$543,809	\$543,809
0002AK	(Deliverable 2-17) Health Care Ad Hoc Tasks: Level of Effort Units	\$1,200,000	\$1,200,000
0002AL	(Deliverable 4-27) Measure Selection and Removal-Related Ad Hoc Tasks	\$207,580	\$207,580
0002AM	(Deliverable 5-1) Core Quality Measures Collaborative (CQMC) Activities Implementation Proposal	\$506,559	\$506,559
0002AN	(Deliverable 6-1) Transition Plan	\$73,308	\$73,308
Total			\$8,861,257

## 9.0 Updates to Policies and Procedures

Pursuant to §1890(b)(5)(A) (iii) the CBE must report "any updates or modifications of internal policies and procedures of the entity as they relate to the duties of the entity ... including—(I) specifically identifying any modifications to the disclosure of interests and conflicts of interests for committees, workgroups, task forces, and advisory panels of the entity. Additionally, the CBE must report relevant interests and any conflicts of interest for members of all committees, workgroups, task forces, and advisory panels, and the total percentage by health care sector of all convened committees, workgroups, task forces, and advisory panels."

In 2024, Battelle developed and posted appropriate forms for nominating interested parties, subject matter experts, and other stakeholders as candidates for committees and workgroups. Additionally, Battelle created forms to collect information on actual, apparent, or potential conflicts of interest (COIs) from nominees, covering both personal financial interests and interests related to specific measures under discussion. Throughout 2024, Battelle did not alter its policies or procedures regarding stakeholder participation or COI disclosures.

According to the Battelle (PQM) Conflict of Interest Policy for Committees, all nominees must complete a general disclosure of interest (DOI) form for each committee they apply to before being seated. This DOI form is reviewed holistically and in the context of the committee's topic area. Nominees are required to complete this general DOI form annually via the PQM website to participate on a committee.

For E&M standing committees, once nominees are selected, Battelle provides them with a measure-specific DOI form at the start of each evaluation cycle. This form helps determine if any members need to recuse themselves from discussions due to prior involvement or relationships relevant to the topic area. Since standing committee members review various measures throughout their term, they must complete the measure-specific DOI form for all measures evaluated in each cycle, as well as related or competing measures, to identify potential conflicts or biases. Members who fail to submit the completed form before evaluation meetings cannot participate in discussions or vote on the measures.

In 2024, Battelle convened approximately 430 volunteer individuals or organizations across 10 multi-stakeholder groups to serve on committees. Figure 24 details the percentage of committee members representing various health care sectors, showing the proportional representation across all current CBE committees hosted by Battelle. Additionally, the CQMC Full Collaborative is represented in this figure through counts of unique organization members, with each member organization having one health care sector or organization type.

Battelle reviewed the disclosures and found no conflicts of interest or financial interests affecting the committees' work, so no mitigations were required.

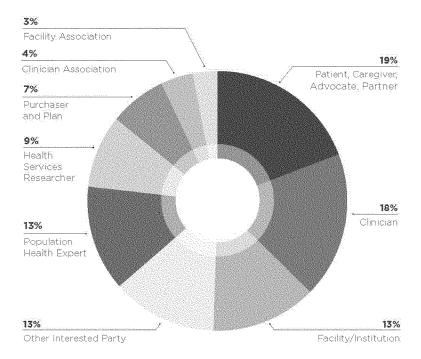


Figure 24. Proportional Representation of Health Care Sectors in PQM Committees and Other Groups in 2024

Complete rosters for all committees, workgroups, task forces, and advisory panels funded through NCDC are located on the  $\underline{PQM \text{ web site}}$ .

### 10.0 Conclusion

In 2024, Battelle, as the world's largest independent, not-for-profit applied science and technology organization, continued to lead the charge in advancing health care quality through its role as a certified consensus-based entity (CBE). The Partnership for Quality Measurement (PQM)™, comprising over 1,200 stakeholders, has been instrumental in shaping the future of health care quality measurement. This report highlights the significant achievements and strategic initiatives undertaken by Battelle's CBE from January 1, 2024, to December 31, 2024.

Battelle's efforts in 2024 were marked by a commitment to burden reduction, transparency, and scientific rigor. The PQM's expansive membership, which includes patients, caregivers, healthcare providers, rural advocates and policymakers, has ensured that a wide range of perspectives are considered in the quality measurement process. The commitment to bring more patients and clinicians to the process has fostered a shared sense of ownership to quality improvement.

Key processes such as the Endorsement and Maintenance (E&M), Pre-Rulemaking Measure Review (PRMR), and Measure Set Review (MSR) have been pivotal in optimizing the CMS measure portfolio. These processes ensure that measures are evidence-based, scientifically sound, and effective in improving health outcomes. Battelle's commitment to continuous improvement is evident in the enhancements made to these processes, such as streamlined timelines, increased engagement, and refined voting structures.

The implementation of the CBE 5-Year Strategic Plan, supported by initiatives like the AI Pilot, Digital-Readiness Assessment, and CBE Portfolio Gap Analysis, underscores Battelle's dedication to reducing the burden of quality measurement while increasing its benefits. By focusing on evidence-based practices and meaningful community engagement, Battelle is well-positioned to lead transformative changes in health care quality measurement and improvement. As Battelle moves forward, it remains committed to evolving its quality measurement strategies to address emerging challenges and opportunities.

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## 12.0 Abbreviations

ACA	Affordable Care Act	LTACH	Long-Term Acute Care Hospitals	
AHIP	American Health Insurance Plans	LTCH	Long-Term Care Hospital	
AHRQ	Agency for Healthcare Research and Quality	MERIT	Measures Under Consideration Entry/Review Information Tool	
Al Pilot ASC	Artificial Intelligence Pilot  Ambulatory Surgical Centers	MIPPA	Medicare Improvement for Patients and Providers Act	
CAHPS	Consumer Assessment of Healthcare Providers and Systems	MIPS	Merit-Based Incentive Payment System	
СВЕ	Consensus-Based Entity	MMS	Measures Management System	
СМІТ	CMS Measures Inventory Tool	MMS Hub	Measures Management System website	
CMS	Centers for Medicare & Medicaid Services	MSR	Measure Set Review	
coı	Conflict of Interest	MUC	Measures Under Consideration	
сQМ	Core Quality Measures	NCDC	National Consensus Development and Strategic Planning for Health Care Quality Measurement	
CQMC	Core Quality Measures Collaborative		Contract	
DOI	Disclosure of Interest	NLP	Neuro Linguistic Programming	
E&M	Endorsement and Maintenance	PA	Preliminary Assessment	
eCQM	Electronic Clinical Quality Measures	PAC/LTC	Post-Acute Care/Long-Term Care	
EHR	Electronic Health Record	PQM	Partnership for Quality Measurement	
EPC	Evidence-Based Practice Center	PRMR	Pre-Rulemaking Measure Review	
ESRD QIP	End-Stage Renal Disease Quality Improvement Program	PRO-PM	Patient-Reported Outcome Performance Measure	
FHIR	Fast Healthcare Interoperability Resources	QPP	Quality Payment Program	
HCBS	Home and Community-Based Services	SDOH	Social Determinants of Health	
HHS	Department of Health and Human Services	SNF	Skilled Nursing Facilities	
HOPD	Hospital Outpatient Department	SSA	Social Security Act	
IMPACT	Improving Medicare Post-Acute Care Transformation Act	STAR	Submission Tool and Repository	
		SUD	Substance Use Disorder	
IRF	Inpatient Rehabilitation Facilities	TEP	Technical Expert Panel	
LLMS	Large Language Models	USCDI	United States Core Data for Interoperability	

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