

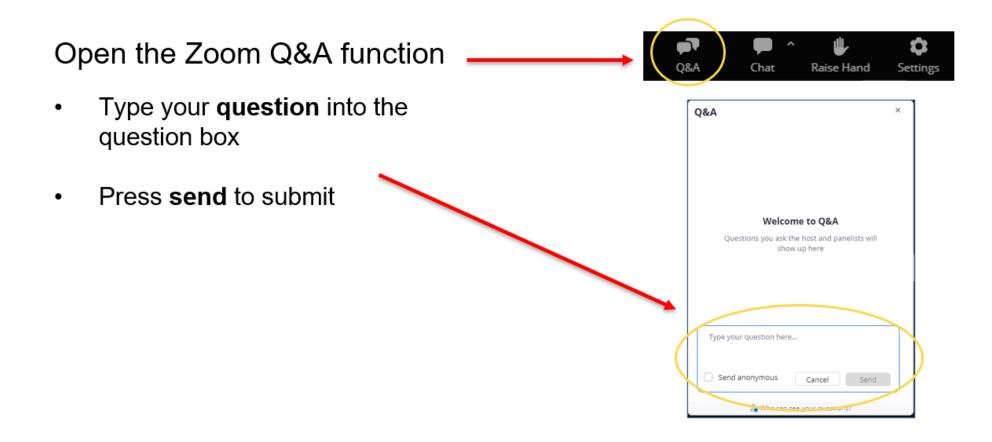


Housekeeping

- All audio lines will be muted during the presentation.
- The meeting is being recorded and will be uploaded to the <u>Pre-Rulemaking Resources Webpage on the CMS Measures</u>

 <u>Management System (MMS) Hub</u> for future viewing.
- Questions will be addressed later in the presentation.

How to ask Questions



Agenda

- Pre-Rulemaking Overview
- Updates to CMS Measures Under Consideration Entry/Review Information Tool (MERIT)
 - What is CMS MERIT?
 - Description of features
 - Updates to CMS MERIT for 2025
 - Guidance on completing required fields
 - eCQM requirement clarifications
- Pre-Rulemaking Measure Review (PR)
- Support & Resources
 - Tour of Pre-Rulemaking webpage
- Questions and Answers

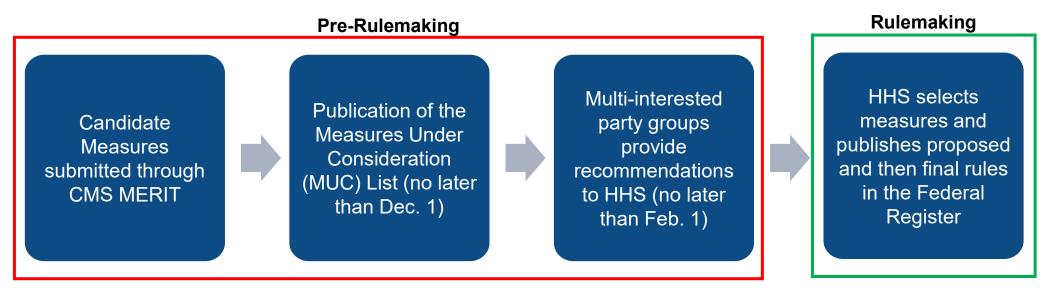




Pre-Rulemaking Overview: Timelines, Trends, and Key Considerations

Pre-Rulemaking Process

Section 3014 of the Patient Protection and Affordable Care Act of 2010 (ACA), created section 1890A of the Social Security Act, which required the U.S. Department of Health and Human Services (HHS) to establish a federal pre-rulemaking process for the selection of quality and efficiency measures for use by HHS.



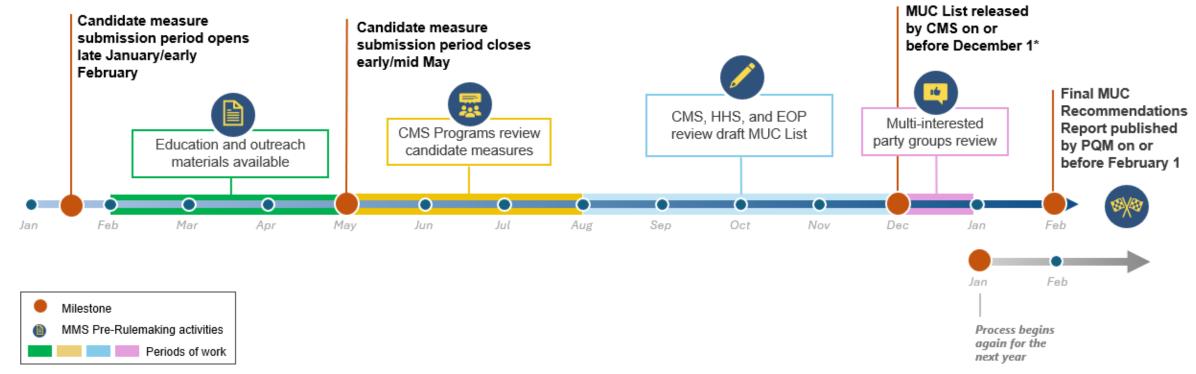
Pre-Rulemaking Programs

The Pre-Rulemaking process for measure selection is used by the following Medicare programs:

- Ambulatory Surgical Center Quality Reporting
- End-Stage Renal Disease Quality Incentive
- Home Health Quality Reporting
- Hospice Quality Reporting
- Hospital-Acquired Condition Reduction
- Hospital Inpatient Quality Reporting
- Hospital Outpatient Quality Reporting
- Hospital Readmissions Reduction
- Hospital Value-Based Purchasing
- Inpatient Psychiatric Facility Quality Reporting

- Inpatient Rehabilitation Facility Quality Reporting
- Long-Term Care Hospital Quality Reporting
- Medicare Promoting Interoperability
- Medicare Shared Savings
- Merit-based Incentive Payment System
- Part C and D Star Ratings
- Prospective Payment System-Exempt Cancer Hospital Quality Reporting
- Rural Emergency Hospital Quality Reporting
- Skilled Nursing Facility Quality Reporting
- Skilled Nursing Facility Value-Based Purchasing

Linear Pre-Rulemaking Timeline



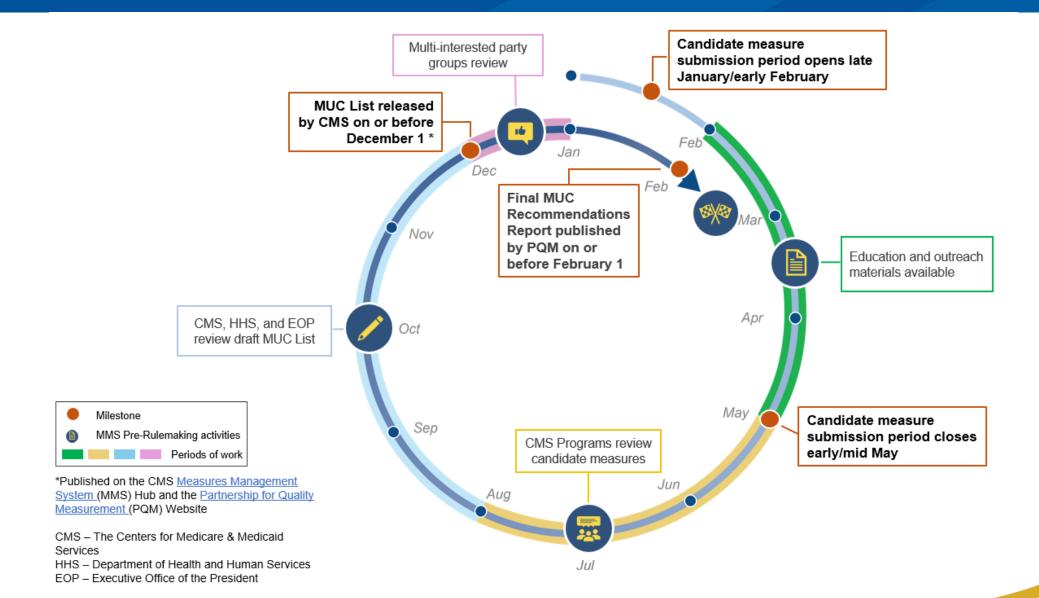
*Published on the CMS Measures Management System (MMS) Hub and the Partnership for Quality Measurement (PQM) Website

CMS - The Centers for Medicare & Medicaid Services

HHS - Department of Health and Human Services

EOP - Executive Office of the President

Cyclical Pre-Rulemaking Timeline



2025 Measure Submission Important Dates



Feb 5, 2025

CMS MERIT opened for measure submissions.



May 1, 2025

CMS MERIT closes for measure submissions.



Dec 1, 2025

2025 MUC List is statutorily required to publish no later than Dec. 1st*

*Published on the CMS <u>Measures Management System</u> (MMS) Hub and the <u>Partnership for Quality Measurement</u> (PQM) website.

Measure Submission Considerations



Measures currently used in CMS programs do not need to go on the MUC List again

Exceptions:

- Measures being expanded into other CMS program(s)
- Measures currently used in a program but underwent substantive changes



Measure specifications may change over time. If your measure has substantively changed, you should submit it again for consideration

Examples of substantive changes could include:

- Intent of measure
- Facility/Setting

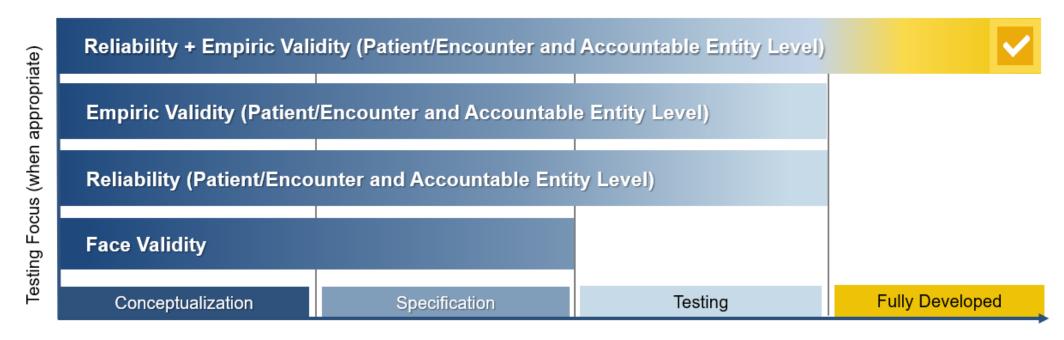
- Data Source
- Level of Analysis

Measure Selection Considerations

- Does the submission align with the quality priorities?
- Is the submission a digital measure? Or an outcome measure?
- Is the candidate measure fulfilling a Meaningful Measure priority gap for this program?
- Does the measure improve upon or enhance any existing measures in the public or private sector? If so, could the original measure be removed?
- Is the measure evidence-based?
- Would the measure be burdensome to operationalize?
- What is the measure's stage of development? Is it fully tested?

Stage of Development

CMS prefers measures that have been fully conceptualized, specified, and tested, but will evaluate measures at all stages.



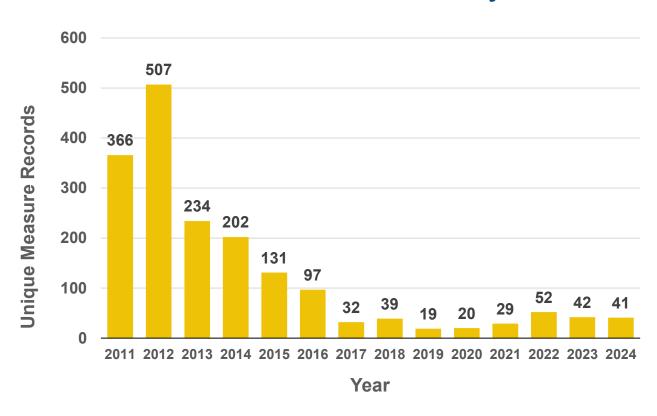
Stages of Development

CMS Program Needs and Priorities

- 2025 MUC List Program-Specific Measure Needs and Priorities Report is posted to the <u>Pre-Rulemaking Resources Webpage on the</u> <u>CMS Measures Management System (MMS) Hub</u>
- The summary for each program contains the following information:
 - Program history and structure
 - High priorities for future measure consideration
 - Program-specific measure requirements

MUC List Historical Trends

Measures Under Consideration by Year



A complete repository of historical MUC Lists and Reports is located at:

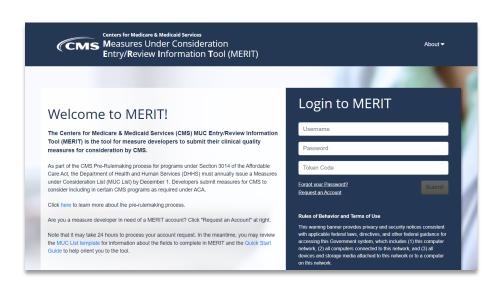
Pre-Rulemaking MUC Lists and Recommendation Reports The Measures Management System (cms.gov)



Updates to CMS MERIT



What is CMS MERIT?



- The Centers for Medicare & Medicaid Services (CMS)
 MUC Entry/Review Information Tool (CMS MERIT) is the
 tool for measure developers to submit their clinical quality
 and efficiency measures for consideration by CMS.
- CMS MERIT is also used for facilitating searches of measures from the current and previous years and structuring the workflow for CMS review of measures submitted to CMS MERIT.
- CMS MERIT opened on February 5th for the 2025 cycle and will close at 8 p.m. ET on May 1, 2025.

CMS MERIT Features

CMS MERIT provides the efficiency and effectiveness of the submission and review process.

Automatic completeness checks

- CMS MERIT ensures all required measure information is submitted.

Save submissions and return later

- Submitters can save and return later to complete measure information.

Review process tracking

- Submitters and reviewers can track progress of their submission(s).

Easy-to-navigate interface

- Designed with human-centered principles for intuitive and user-friendly navigation.

Copy and Paste Functionality

- Ability to copy and paste from Word docs into submission(s).

Ability to print .pdf of submissions

- Print and/or save a copy of submission(s) in PDF.

Updates to CMS MERIT for 2025



Steward Information Shifted: Now at the start of the submission process, enabling submitters to input necessary data and include collaborators early on.



Language Updates: MAT and Bonnie language replaced with MADiE language, eCQM submission guidance updated for clearer attachment requirements.



New Proprietary Questions: Asking about proprietary or licensed measure aspects, inclusive of potential licensing fees for CMS or Measured Entities, calling for explanations where needed.

Updates to CMS MERIT for 2025: Composite/Survey Measure Enhancement

- Previous Process: Submitters had to enter basic, high-level information into CMS MERIT and attach additional documentation or supplemental materials to the CMS MERIT system for each component or survey-based measure to submission.
- New Process: Enables submitters to directly input all necessary information for each component or survey-based measure into CMS MERIT submissions.

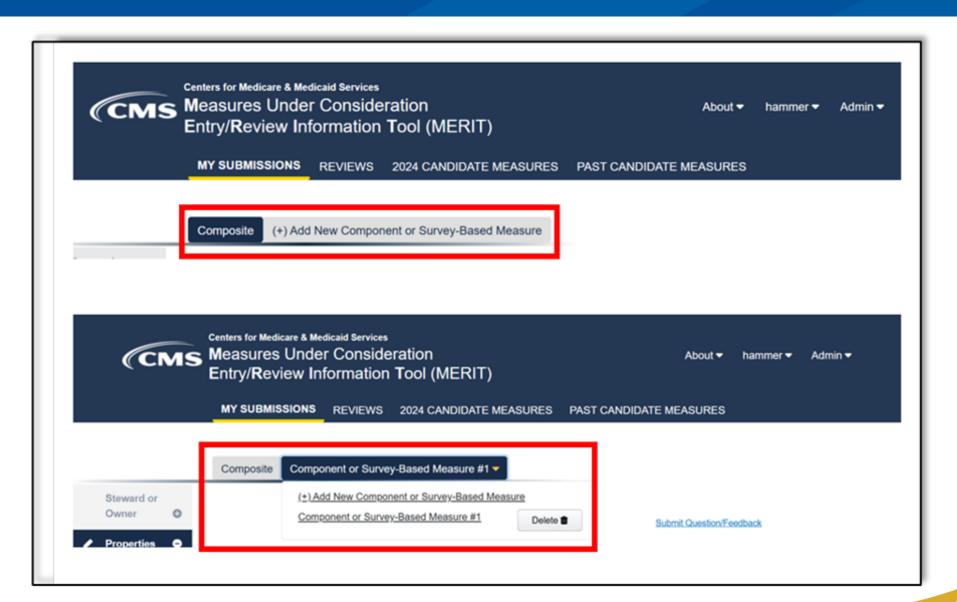
Benefits:

- Streamlines the submission process.
- Ensures more efficient and comprehensive submissions.
- Allows submitters to convey measures more effectively to CMS.
- Facilitates a fuller understanding of the measure by CMS during the review process.

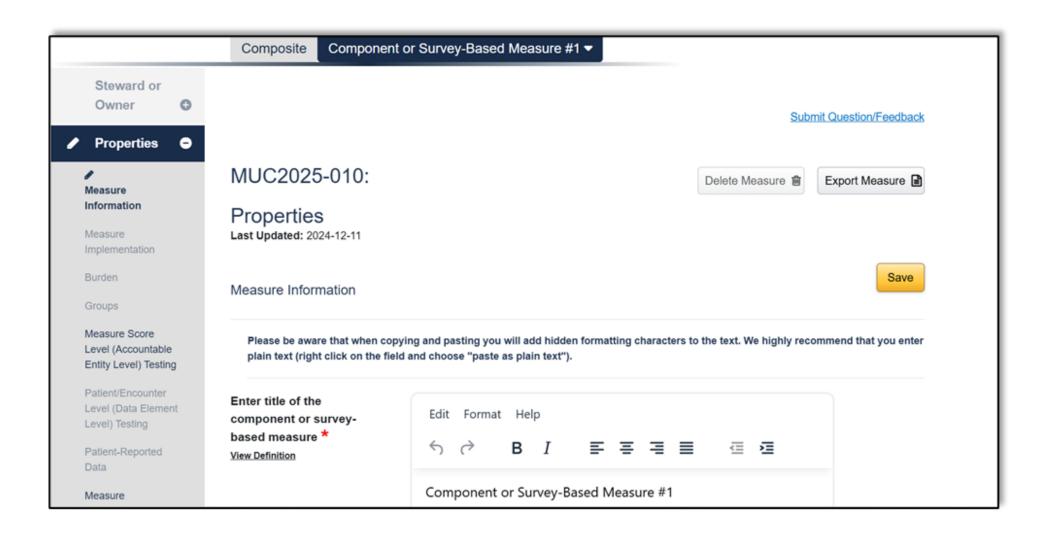
Updates to CMS MERIT for 2025: Composite/Survey Measure Enhancement Cont.

Is the measure a composite, survey, and/or a paired measure? * View Definition		Select / Unselect All				
	0	Yes, this is a composite measure No, this is not a composite, survey, or a paired measure		Yes, this is a survey measure		Yes, this is a paired measure
	If you choose composite or survey, a "Component or Survey-Based Measure" tab will appear at the top of the screen. Navigate to this screen to answer the component and survey-based questions.					

Updates for 2025: Composite/Survey Measure Enhancement Cont.



Updates to CMS MERIT for 2025: Composite/Survey Measure Enhancement Cont.



Updates to CMS MERIT for 2025: Section 508-Compliant Attachments

- CMS expects strongly recommends all applicable testing documents to be Section 508-Compliant before submission.
 - Attachments are made public to improve transparency
 - Adherence to 508 standards allows documents to be accessible to those with disabilities
 - Allows for a full review of the measures by the CBE PRMR recommendation committees
- Non-compliant documents will be expected to be remediated in conjunction with the MMS team and the submitter prior to the MUC list being finalized.

Resources:

- Section 508.gov: https://www.section508.gov/
- CMS Creating Accessible Products: https://www.cms.gov/data-research/cms-information-technology/section-508-and-cms/public/creating-accessible-products
- HHS Accessibility & Section 508 Policy: https://www.hhs.gov/web/section-508/accessibility-checklists/index.html



Required Data Fields

Key Goals for 2025 Updates:

- Support CMS in addressing the U.S. Government Accountability Office recommendations¹ relative to systematic measure assessment aligned with CMS quality objectives
- Align with CBE criteria² and CMS MMS Hub's Blueprint Content³ where feasible
- Reduce measure developer burden and improve flow
- Streamline the collection of measure data

¹US Government Accountability Office. Health Care Quality: CMS Could More Effectively Ensure Its Quality Measurement Activities Promote Its Objectives. Washington, DC: US Government Accountability Office; 2019. https://www.gao.gov/assets/710/701512.pdf

² CBE criteria include pre-rulemaking review (PRMR) and endorsement and maintenance (E&M). https://p4qm.org

³ https://mmshub.cms.gov/blueprint-measure-lifecycle-overview

Required Data Fields Cont.

Refinements for 2025:

Key Refinements Made to Data Fields:

- Updated capability to include composite or survey-based measures directly rather than as attachments
- Clarified guidance language (e.g., clarified MIPS testing submission requirements and how to report clinician and/or group level testing)
- Updated selection options (e.g., added "Mixed Logistic Regression" as a Signal-to-Noise reliability testing example, separated "Yes, this is a composite or survey measure" into two distinct options)

Required Data Fields Example: Is the measure a composite, survey, and/or a paired measure?

Added capability to input data for composite and survey measures directly

Is the measure a composite, survey, and/or a paired measure? *

View Definition

Is the measure a composite, survey, and/or a paired measure?

Select all that apply.

A composite measure contains two or more individual measures, resulting in a single measure and a single score. This includes index measures.

A survey measure refers to a type of performance measure that is derived from data collected through surveys.

Paired measures have different measure scores, but results require them to be reported together to be interpreted appropriately. Note: Individual measures comprising a paired measure must be submitted individually. Select / Unselect All

Yes, this is a composite measure

Yes, this is a survey measure

Yes, this is a paired measure

No, this is not a composite, survey, or a paired measure

If you choose composite or survey, a "Component or Survey-Based Measure" tab will appear at the top of the screen. Navigate to this screen to answer the component and survey-based questions.

Required Data Fields Example: Level of Analysis

Updated guidance on level of analysis and how to submit Measure Score Level (Accountable Entity Level) testing results if multiple levels are selected

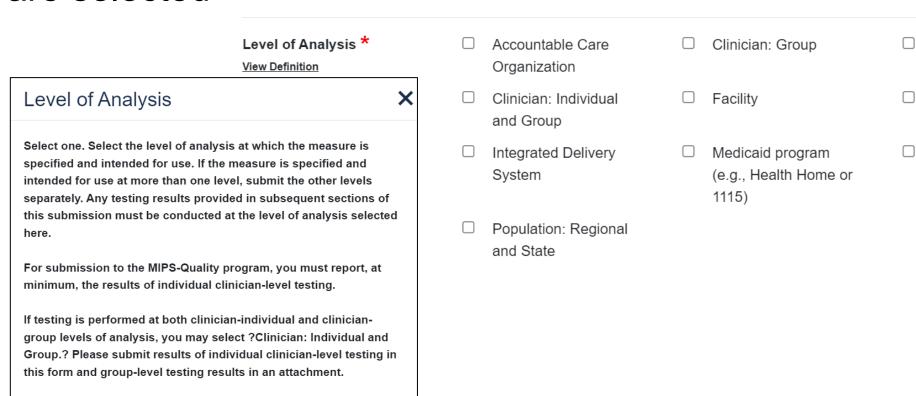
Clinician: Individual

Community, County or

Health Plan

Population:

Citv



testing is sufficient.

For submission to the MIPS-Cost program, clinician group-level

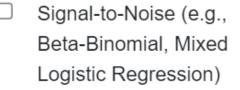
Required Data Fields Example: Reliability: Type of Analysis

Added Mixed Logistic Regression as an example for Signal-to-Noise reliability testing

Reliability: Type of analysis



View Definition



 □ Random Split-Half □ Correlation





Select all that apply.

Signal-to-noise (or inter-unit reliability) is the precision attributed to an actual construct versus random variation (e.g., ratio of between unit variance to total variance) (Adams J. The reliability of provider profiling: a tutorial. Santa Monica, CA: RAND; 2009.

http://www.rand.org/pubs/technical_reports/TR653.html.).

Random split-half correlation is the agreement between two measures of the same concept, using data derived from split samples drawn from the same entity at a single point in time.



eCQM Readiness, Step 1: Specification

- Measure Authoring Development Integrated Environment (MADiE) output to include Health Quality Measure Format (HQMF) human readable files
- MADiE test case export achieving 100% passing and 100% coverage
- Value sets published in the Value Set Authority Center (VSAC)
- eCQM Fast Healthcare Interoperability Resources (FHIR) specification output from MADiE with MADiE test cases included
 - Please note: 2025 is the final year that FHIR specifications will be optional

eCQM Readiness, Step 2: Testing

- Reliability and validity testing that meets the definition of a <u>fully</u> developed measure
- Feasibility testing documented on the feasibility scorecard

eCQM Readiness, Step 3: Steward Expectations

- A measure steward is expected to:
 - Understand and apply eCQM standards, including Quality Data Model (QDM), Clinical Quality Language (CQL), and FHIR
 - Make and test technical changes using eCQM tools, including MADiE and VSAC
 - Support responses to interested party's questions on the measure throughout the year

eCQM Readiness, Step 3: Steward Expectations, continued

- A measure steward is expected to:
 - Participate in the eCQM Annual Update process, which is distinct from update cycles for other collection types and may begin at a different time than other collection types
 - Adhere to the timelines and processes set forth for the eCQM Annual Update for both QDM-based and FHIR-based specifications
 - Maintain and update value sets used for the measure in VSAC
 - Maintain documents used to support measure updates (e.g., technical release notes, measure flows)

eCQM Readiness: Notes and Resources

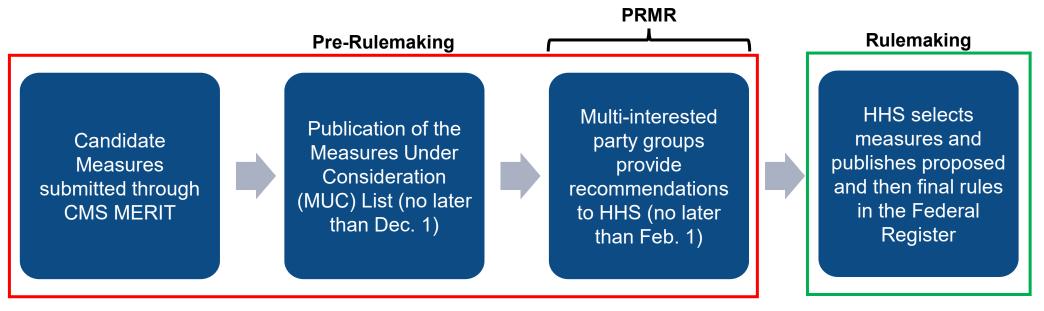
- MAT and Bonnie were decommissioned on June 28, 2024. Prior to this date, measure stewards successfully migrated all eCQMs, libraries, and test cases to MADiE.
- As part of CMS's transition to digital quality measures, CMS is transitioning to using HL7 FHIR Data Model and FHIR Reporting Requirements for representing and reporting eCQM data. Measure stewards will need to support maintenance of both QDM- and FHIR-based eCQMs during this transition.
- Resources:
 - eCQI Resource Center: https://ecqi.healthit.gov/
 - MADiE: https://www.emeasuretool.cms.gov/madie-mvp
 - Value Set Authority Center: https://vsac.nlm.nih.gov/
 - CMS Measures Management System: https://mmshub.cms.gov/



Pre-Rulemaking Measure Review (PRMR)

Pre-Rulemaking Process: PRMR

Section 3014 of the Patient Protection and Affordable Care Act of 2010 (ACA), created section 1890A of the Social Security Act, which required the U.S. Department of Health and Human Services (HHS) to establish a federal pre-rulemaking process for the selection of quality and efficiency measures for use by HHS.



PRMR and MSR Guidebook

- The guidebook serves as a resource to all parties who are interested in these processes and includes details on the following:
 - PRMR and MSR activities, processes, and their associated timelines
 - Summary of committee compositions
 - Measure selection and continued use criteria

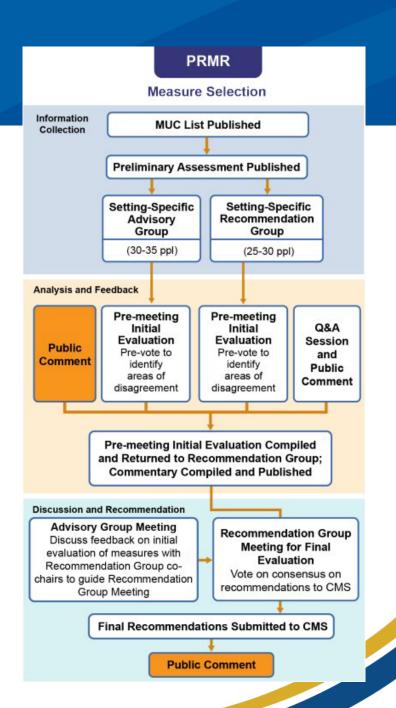


PRMR Process

The PRMR process builds consensus regarding MUC List measures as to whether they are appropriate for consideration for CMS quality reporting programs and value-based programs

Three major phases:

- 1. Information collection
- 2. Analysis and feedback
- 3. Discussion and recommendation



Measure Developer's Role in PRMR

Meeting/Activity	Timeframe	Purpose/Developer Role			
Optional submission of updated testing results for measures under consideration	August/September	Ensure PRMR committees have access to updated/final testing information during their reviews			
Developer/Steward Education Meeting	October	Review PRMR process, evaluation criteria, and key milestones.			
Review Preliminary Analyses	October/November	Ensure accuracy of preliminary analysis of measure information according to PRMR evaluation criteria prior to publication			
Listening Sessions	Mid-December	Opportunity for spoken public comment on measures. Measure developers may be invited by CMS leads to respond to questions raised.			
Advisory Group Meetings	Early January	Opportunity for (non-voting) Advisory Group members to provide feedback to committee co-chairs. Measure developers are invited to listen in as members of the public			
Recommendation Group Meeting	Mid-Late January	Discussion and voting to recommend measures for further federal rulemaking. Measure developers may be invited by CMS leads to respond to questions raised.			



CMS MERIT Support



Quick Start Guide and 2025 MERIT Data Template are available for download on log in page



CMS MERIT Tips &
Tricks Session
April 8
12:00 P.M. ET

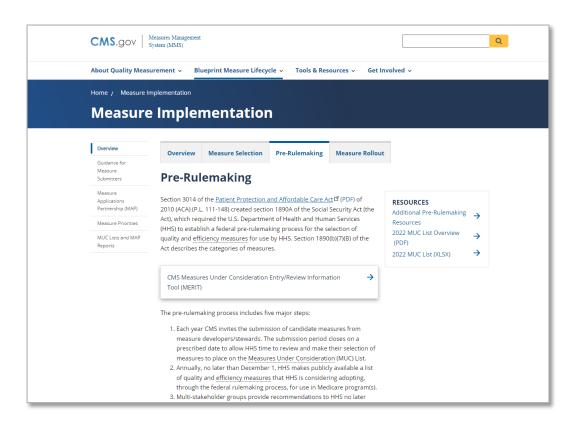


Contact MMSsupport@battelle.org
with CMS MERIT questions

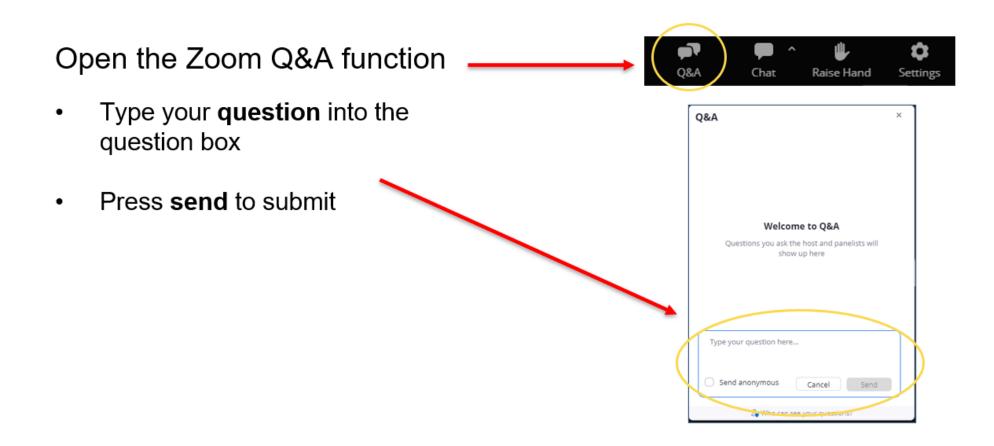
Pre-Rulemaking Resources

Tour of Pre-Rulemaking Webpage

Pre-Rulemaking | The Measures Management System (cms.gov)



Questions





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