

2023 Pre-Rulemaking Kickoff

Measures Under Consideration Overview



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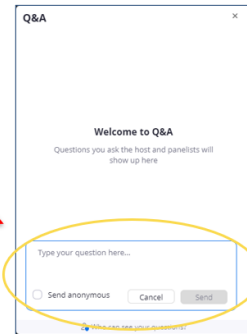
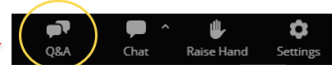
Housekeeping

- All audio lines will be muted during the presentation.
- The meeting is being recorded and will be uploaded to the Centers for Medicare & Medicaid Services (CMS) website for future viewing.
- Questions will be addressed later in the presentation.

Questions

Open the Zoom Q&A function

- Type your **question** into the question box
- Press **send** to submit

A screenshot of the Zoom Q&A interface. It shows a 'Welcome to Q&A' message and a text input field with the placeholder 'Type your question here...'. Below the input field is a 'Send anonymous' checkbox and two buttons: 'Cancel' and 'Send'. The 'Send' button is highlighted with a yellow oval. A red arrow points from the 'Press send to submit' instruction to this 'Send' button.

Agenda

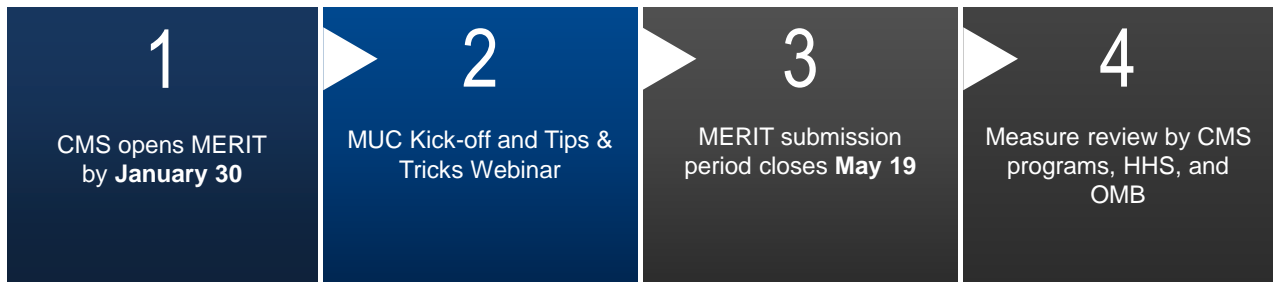
- **Pre-Rulemaking Process**
- **CMS Measures Under Consideration Entry/Review Information Tool (MERIT)**
 - Description of features
 - Guidance on completing required fields
- **Pre-Rulemaking Resources**
 - Tour of Pre-Rulemaking website
- **Questions and Answers**



Overview of Pre-Rulemaking Process and Timeline

Pre-Rulemaking Phase I

- Pre-Rulemaking submission steps
- Post submission activities
 - Developer Support to CMS
 - If requested by CMS, submit additional information (i.e. updated testing data) to inform review processes
 - Attend multi-stakeholder review meetings if their measure is being reviewed



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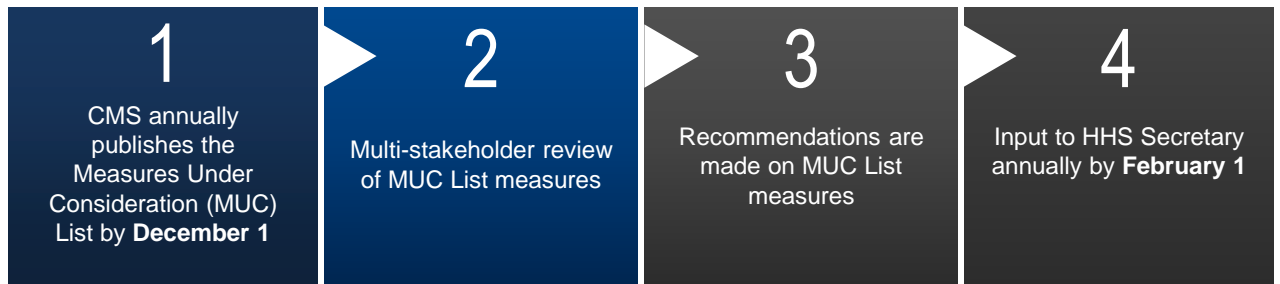
Statutory Reference: Section 3014 of the Patient Protection and Affordable Care Act and sections 1890 and 1890A of the Social Security Act

Section 3014 of ACA created a new section, 1890A of the SSA that requires HHS to establish a federal pre-rulemaking process for the selection of quality and efficiency measures for use by HHS. The pre-rulemaking process that satisfies the statutory requirement will be discussed in this slide deck, which is broken up into two phases, each containing four major steps.

Phase 1—CMS opens MERIT and conducts education for measure submission, such as this webinar, and concludes the submission period and begins measure review by CMS programs, HHS and OMB.

Pre-Rulemaking Phase II

- Phase II of this process includes multi-stakeholder review and recommendations to HHS regarding measures being considered.
- Details on the transition of current work and future activities will be provided in the coming weeks.



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Phase 2—CMS annually publishes the MUC List by December 1st. The list undergoes a multi-stakeholder group review/recommendations for selection of measures to HHS annually no later than February 1st. Details on the transition of this work related to the multi-stakeholder review and future activities will be communicated in the coming weeks.

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

Pre-Rulemaking Process — Medicare Programs

The pre-rulemaking process applies to measures being submitted for specific Medicare quality programs.

Medicare Programs	Medicare Programs continued
Ambulatory Surgical Center Quality Reporting	Inpatient Rehabilitation Facility Quality Reporting
End-Stage Renal Disease Quality Incentive	Long-Term Care Hospital Quality Reporting
Home Health Quality Reporting	Medicare Promoting Interoperability
Hospice Quality Reporting	Medicare Shared Savings
Hospital-Acquired Condition Reduction	Merit-based Incentive Payment System
Hospital Inpatient Quality Reporting	Part C and D Star Rating
Hospital Outpatient Quality Reporting	Prospective Payment System-Exempt
Hospital Readmissions Reduction	Cancer Hospital Quality Reporting
Hospital Value-Based Purchasing	Rural Emergency Hospital Quality Reporting
Inpatient Psychiatric Facility Quality Reporting	Skilled Nursing Facility Quality Reporting
	Skilled Nursing Facility Value-Based Purchasing

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Not all CMS quality initiatives go through the pre-rulemaking process; only the 20 Medicare quality programs listed here. Other CMS quality initiatives follow different processes for the selection and implementation of their measures.

Measure Selection Consideration

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 domain 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, its state of development, and tested?
- Would the measure be burdensome to operationalize?
- Is the measure endorsed by a consensus-based entity?

Fully Developed Measure Definition

Fully Developed Measure Criteria:

- Patient/encounter-level testing, when appropriate, for each critical data element has been completed and no changes to the measure specifications are needed based on the results.
- Reliability testing, when appropriate, at the accountable entity level has been completed and no changes to the measure specifications are needed based on the results.
- Empiric validity testing, when appropriate, at the accountable entity level has been completed and no changes to the measure specifications are needed based on the results.
 - Completion of face validity testing as the sole type of validity testing does not meet the criteria for Fully Developed. However, face validity will be accepted on a temporary basis for new measures (i.e., those that are not currently in use in CMS programs and undergoing substantive changes) only.

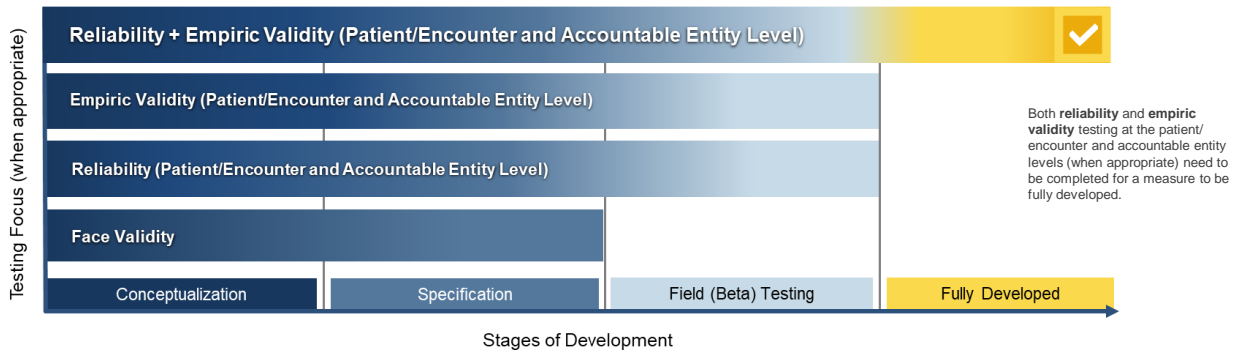
Additionally, for measures based on survey data or patient-reported tools, (including Patient-Reported Outcome Performance Measures (PRO-PMs)), the following must also be true:

- The survey or tool has been tested and no changes to the instrument are needed based on the results.

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This slide outlines the parameters of a CMS “fully developed” measure, highly preferred for submission/consideration on the MUC List. To proceed and submit a measure that is *not* fully developed, provide additional details as to the development status of the measure, but in order to check the “fully developed” box in CMS MERIT the candidate measure must meet the criteria listed here.

Conceptual View of Fully Developed Measures



CMS will evaluate measures at all stages of development, but fully developed measures are preferred.

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This graphic illustrates the various stages of measure development and the level of testing required to achieve a fully developed measure. Clearly, CMS prefers that developers submit measures that are fully developed; however, measures at all stages of development are welcome for submission to MERIT for consideration on the MUC List.

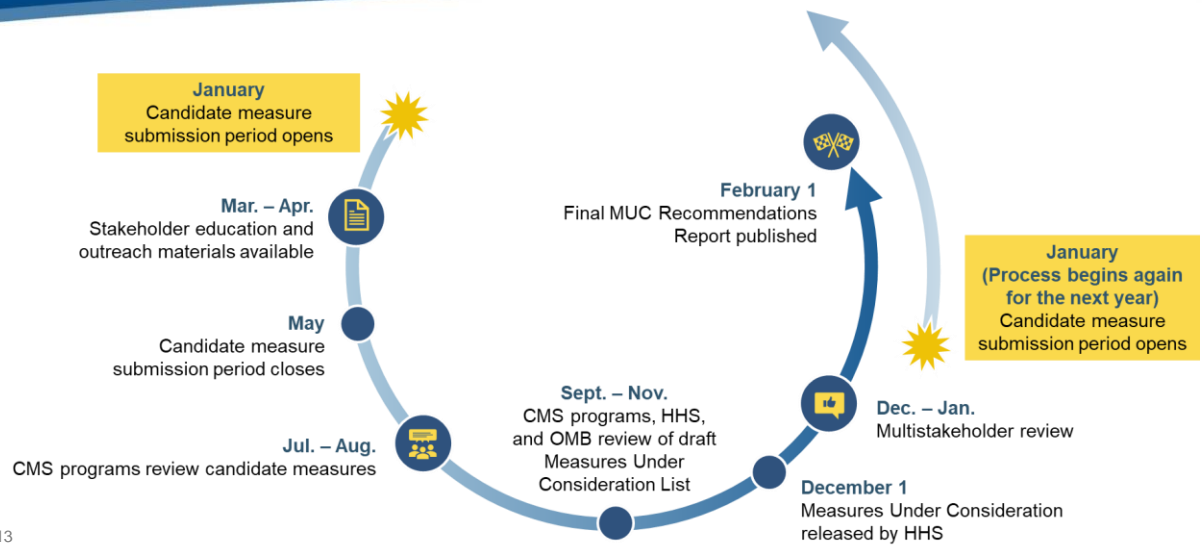
CMS Program Needs and Priorities

- **2023 MUC List Program-Specific Measure Needs and Priorities Report is posted to the [CMS Pre-Rulemaking Website](#)**
- **The summary for each program contains the following information:**
 - Program history and structure
 - Information about number and type of current measures
 - High priorities for future measure consideration
 - Program-specific measure requirements

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The state of development of the measure is a consideration CMS takes into account when reviewing measures submitted for the MUC List. Programs part of the pre-rulemaking process annually identify their needs and priorities for measurement.

Measure Submission, Review, and Publication Process

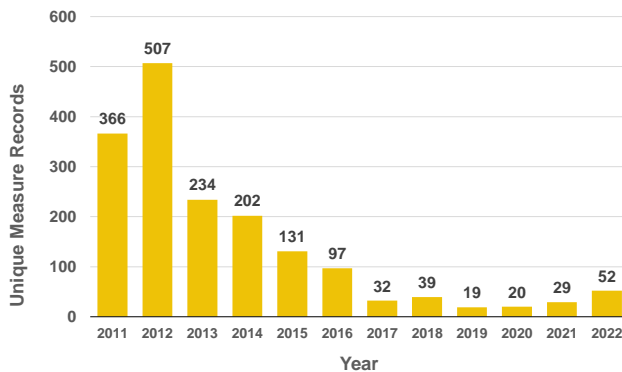


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This circular timeline expands on the two phases of pre-rulemaking, where they overlap, and how the process repeats each year. Notably, the full pre-rulemaking process extends beyond the year, and there is often pre-rulemaking activity related to multiple cycles ongoing at any given point in the calendar year.

MUC Submission Historical Trends

Measures Under Consideration by Year



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

[Pre-Rulemaking MUC Lists and MAP Reports](#)
[The Measures Management System](#)
([cms.gov](https://www.cms.gov))

This slide provides information about past pre-rulemaking cycles. Clearly depicted is a trend towards decreasing numbers of MUC List measures over time. This is due to improved communications regarding measure needs and priorities, including the prioritization of outcome, patient-centered and patient-reported measures.

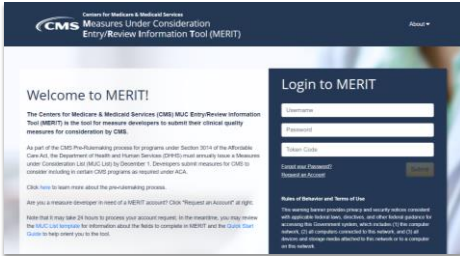
Reflections from 2022

- Successful launch of CMS MERIT in 2022
- Increase in candidate measures accepted to MUC List in 2022
- Continued emphasis on testing results in measure evaluation
- CMS continues to focus on measure priorities like including more outcome measures, patient reported outcomes, and digital measures



CMS MERIT

Measure Submissions



- 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 MERIT.
- CMS MERIT opened on January 30 for the 2023 cycle and is **open for submissions until 8pm ET on May 19**.

CMS MERIT Features

CMS MERIT offers several features that have improved the submission and review process



Automatic completeness checks

CMS MERIT checks for required measure information



Save submissions and return later

Submitters can save and return later to complete measure information



Review process tracking

Submitters and reviewers can track progress



Easy-to-navigate interface

Incorporates human-centered design principles

New Features for 2023

**Additional
functionality
added this year:**

Improved field-level language

Easily identify parent-child questions

Formatted text and characters in open fields

Ability to copy and paste from word doc

Clear email notifications

MUC ID and measure title included in emails for status updates and comments

Print submission

Ability to print and save submission(s) in PDF

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Required fields in CMS MERIT noted with a red asterisk throughout the tool remain unchanged. These asterisk fields must be completed to submit a measure.

Required Data Fields

Key Goals for 2023 Updates:

- Support CMS in addressing the U.S. Government Accountability Office recommendations relative to systematic measures assessment aligned with CMS quality objectives
- Align with CBE criteria
- Reduce measure developer burden and improve flow
- Capture discrete data fields to standardize and streamline the collection of measure data

Required Data Fields

Refinements for 2023:

Key Refinements Made to Data Fields:

- Capture required types of statistical testing for Measure Score Reliability
- Streamlined “Meaningful to Patients and Clinicians” in single section
- Removed estimated impact on healthcare costs
- Enhanced guidance to clarify measure development and submission requirements

Required Data Fields: Examples

- Click "View Definition" to access additional guidance clarifying measure development and submission requirements

Does the provider workflow have to be modified to collect additional data needed to report the measure? *

☐ Yes ☐ No

[View Definition](#)

Definition

Select one.

If workflow modifications required moderate to significant additional data entry from a clinician or other provider to collect the data elements to report the measure because data are not routinely collected during clinical care or EHR interface changes were necessary, select "Yes."

If workflow modifications required no, or limited, additional data entry from a clinician or other provider to collect the data elements to report the measure because data are routinely collected during the clinical care and no EHR interface changes were necessary, select "No."

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Depicted here is an example related to the last point, specifically "enhanced guidance." The data fields in MERIT include a link to view definitions under the item itself as shown here. If you click this link, you will see the guidance for that field. In this particular example you see that the refined guidance for this item provides more detail on how to select your response.

2023 New Required Fields

New Fields for 2023:

New Fields Added to:

- Expand discrete fields for measure performance
- Accommodate paired measures and measures with multiple scores
- Capture data element testing summarized at numerator- and denominator-level
- Incorporate evidence for inappropriate use measures
- Clarify primary and secondary Meaningful Measures 2.0 priorities
- Include additional information regarding risk adjustment and stratification

Required Data Fields: Examples

- Risk adjustment section has been revised to include questions on the conceptual model and stratification
 - The revised section encompasses all MERIT questions related to risk stratification and collects additional information about the methodology.
 - Skip logic applied to new sections reduces submission burden.

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The risk adjustment section includes questions on the conceptual model and stratification, and therefore this approach more closely aligns with the CBE risk model development process. This section now includes all questions in MERIT related to risk stratification and collects additional information about the methodology. Even though there are additional questions this year, the use of conditional skip logic aims to reduce submission burden so that certain questions are only asked where relevant.

Required Data Fields: Example



Centers for Medicare & Medicaid Services
Measures Under Consideration
Entry/Review Information Tool (MERIT)

Characteristics

Last Updated:

Risk Adjustment and Stratification

Was risk adjustment and/or stratification considered? *

☒ Yes

☐ No

[View Definition](#)

Was a conceptual model outlining the pathway between patient risk factors, quality of care, and the outcome of interest established? *

☐ Yes

☐ No

[View Definition](#)

Is the measure risk adjusted? *

☐ Yes

☐ No

[View Definition](#)

Is the measure recommended to be stratified? *

☐ Yes

☐ No

[View Definition](#)

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Depicted here is a screenshot illustrating in more detail the expanded risk adjustment section. So for the first item shown here, a “yes” response will open a subsequent related question. If you select “no” for this first item, the conditional logic will skip the subsequent questions asking about the risk adjustment and/or stratification approach. The aim here is to collect comprehensive measure data without adding unnecessary burden on the submitter.

CMS MERIT Support



Quick Start Guide and
**MS Word template of
measure guidance** are
available for download
on log in page



**CMS MERIT Tips &
Tricks Session**
April 11
12:00 PM Eastern



Contact MMSSupport@battelle.org
with CMS MERIT questions

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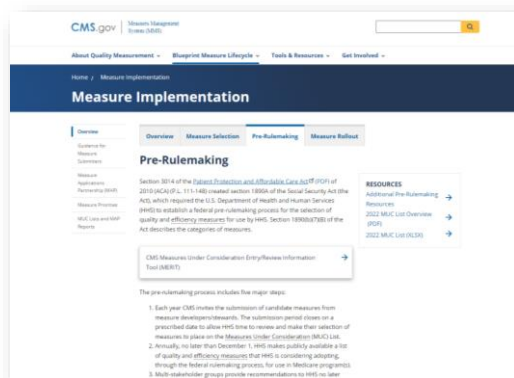
For assistance with CMS MERIT, locate the QuickStart Guide and the Word template containing the CMS MERIT fields on the CMS MERIT login page, which does not require a login to access these resources.

The “CMS MERIT Tips & Tricks” session will review the features of the tool on April 11th. For questions not addressed in the guidance materials, email MMSSupport@battelle.org. That is the inbox for CMS MERIT questions, as well as any general questions about the pre-rulemaking process and requirements.

Pre-Rulemaking Resources

Tour of Pre-Rulemaking Website

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



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Table of contents—Navigate various sections containing the content addressed in this slide deck.

Overview—Background of statutory requirements and the major steps in the pre-rulemaking process.

Guidance of measure submitter's—Deadline for this year's MERIT submission close which is May 19th.

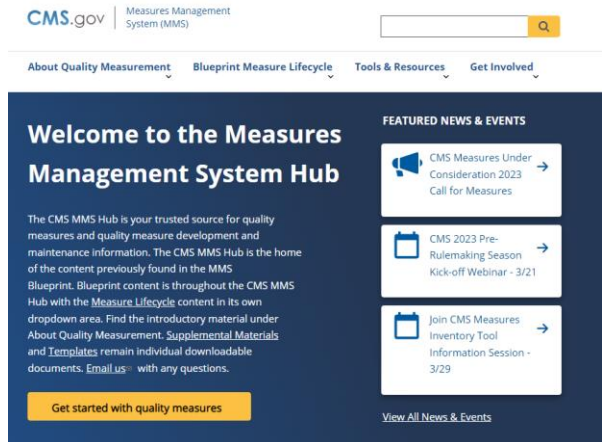
Measure priorities section—Contains previously published MUC Lists dating back to 2011.

Resources—FAQ document summarizes much of this slide deck, along with specific requirements for eQMs and submissions to the MIPS program. The Word template contains all the fields of CMS MERIT for download to draft your responses before inputting your information into CMS MERIT. Also posted are the slides from today's webinar, along with the recording of this webinar as well as the Tips & Tricks webinar once available, along with the 2023 MUC List program-specific Needs and Priorities document.

CMS MMS Hub

<https://mmshub.cms.gov/>

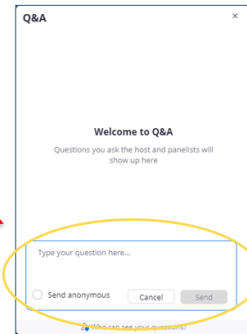
- Launched May 24, 2022
- Integrates the MMS Blueprint and the previous MMS website into a comprehensive, user-friendly format



Questions?

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- Type your **question** into the question box
- Press **send** to submit



Poll

We want your feedback!
Please complete the poll
to let us know how were
doing.



Contacts for Pre-Rulemaking

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