



PUBLIC WEBINAR

# 2024 Pre-Rulemaking Public Webinar

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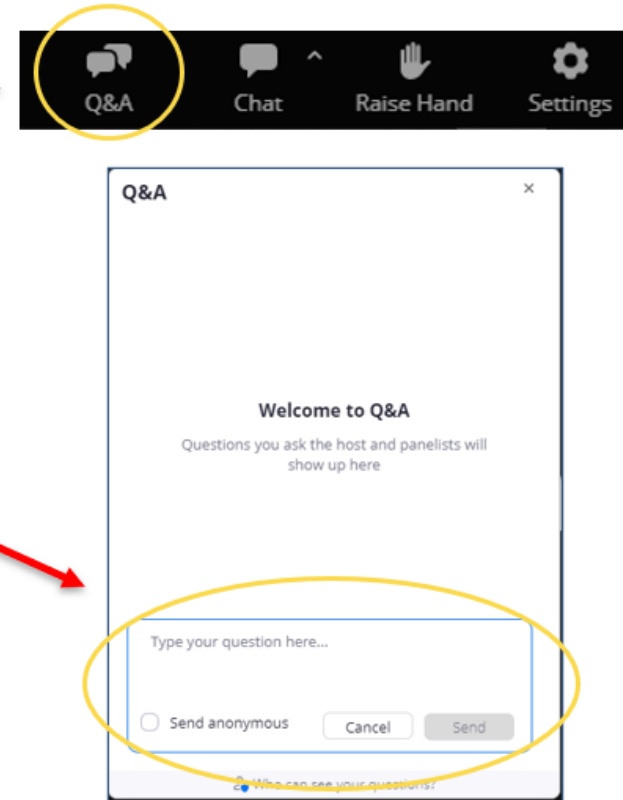
# Housekeeping

- All audio lines will be muted during the presentation.
- The meeting is being recorded and will be uploaded to the [Pre-Rulemaking Resources Webpage on the CMS Measures Management System \(MMS\) Hub](#) 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



# Agenda

- **Pre-Rulemaking Process**
- **CMS Measures Under Consideration Entry/Review Information Tool (MERIT)**
  - Description of features
  - 508 compliant attachments
  - Guidance on completing required fields
  - eCQM requirement clarifications
- **PRMR Review**
- **Pre-Rulemaking Resources**
  - Tour of Pre-Rulemaking webpage
- **Questions and Answers**

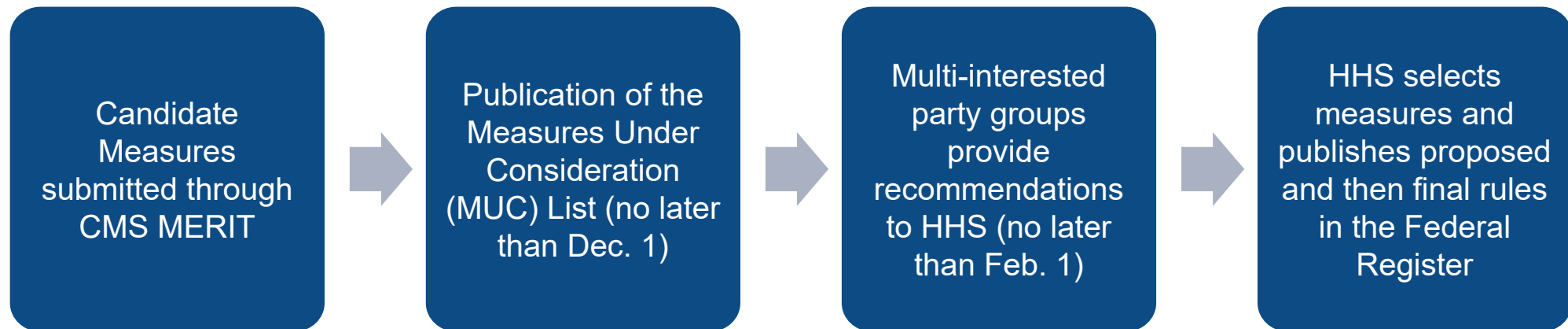




# Overview of Pre-Rulemaking Process and Timeline

# 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:

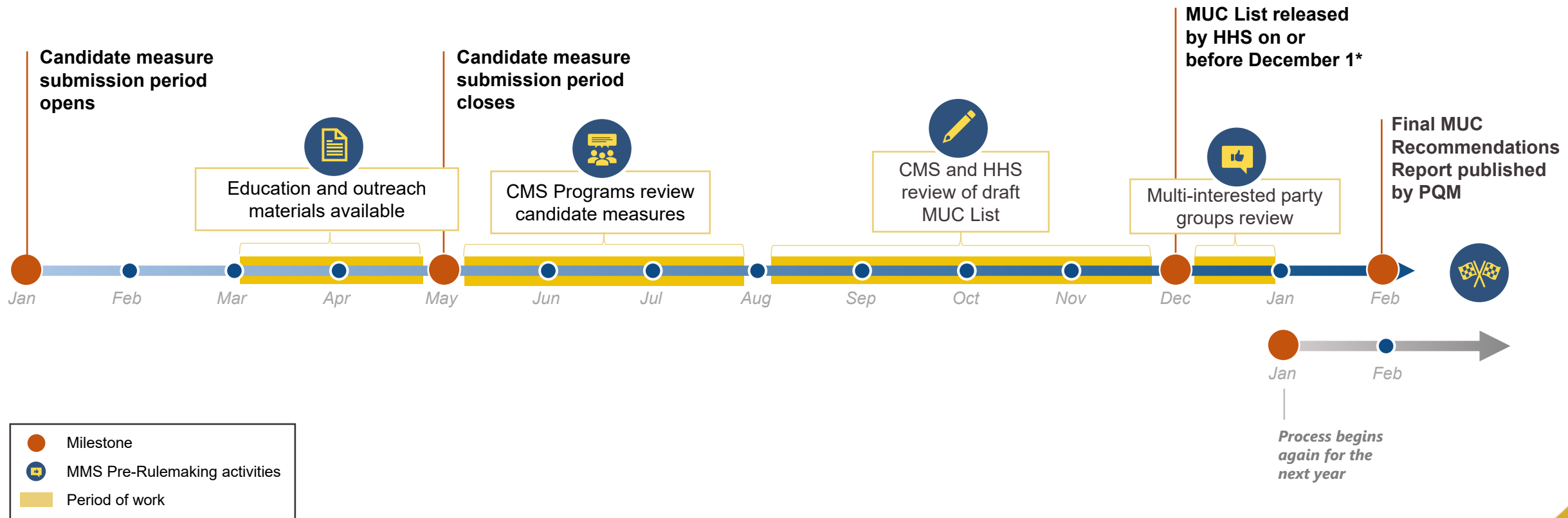
- Ambulatory Surgical Center Quality Reporting
- End-Stage Renal Disease Quality Incentive
- Home Health Quality Reporting
- Hospice Quality Reporting
- Hospital-Acquired Condition Reduction
- Hospital Inpatient Quality Reporting
- Hospital Outpatient Quality Reporting
- Hospital Readmissions Reduction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



# Pre-Rulemaking Timeline

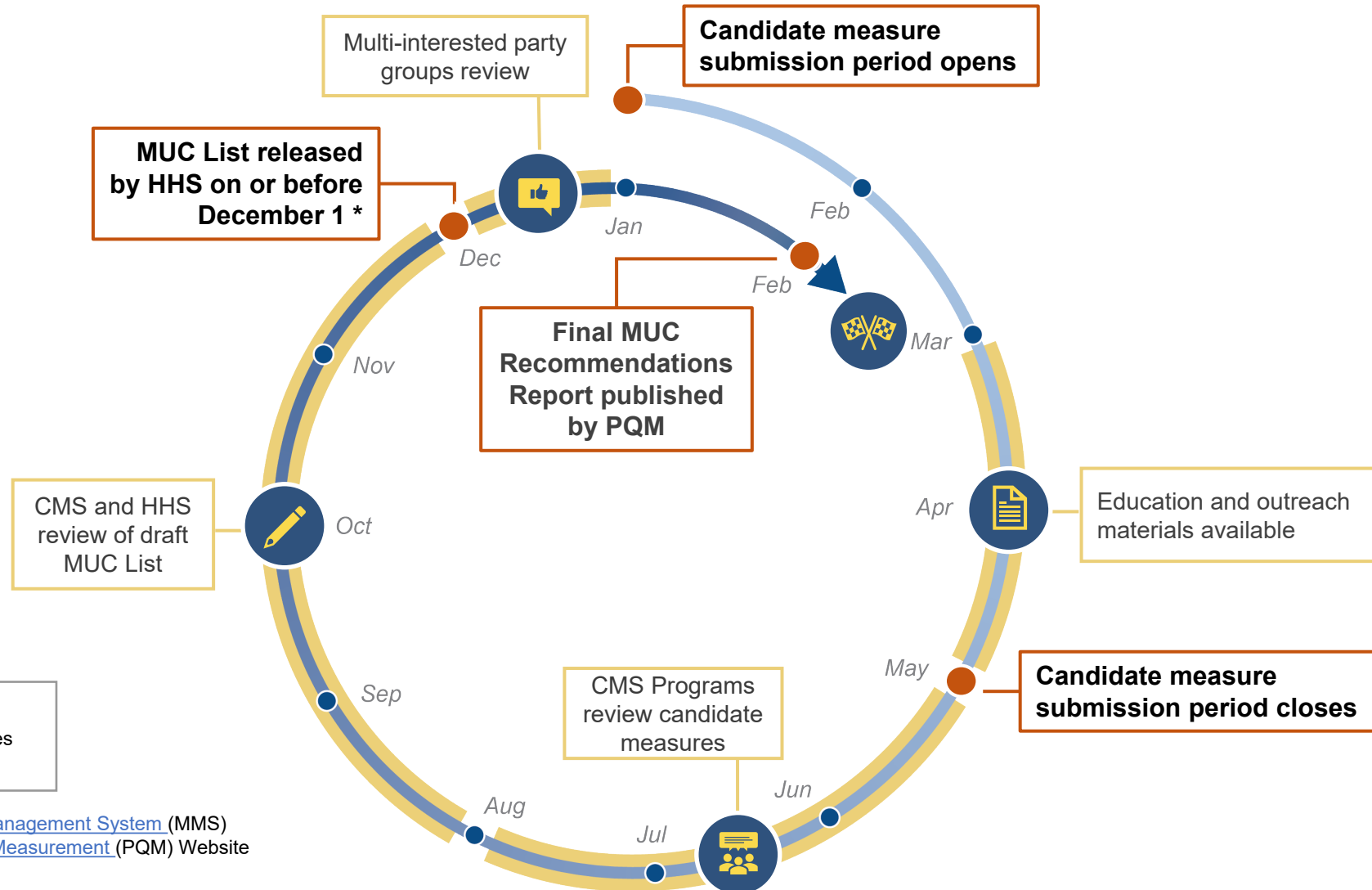


# Linear Pre-Rulemaking Timeline



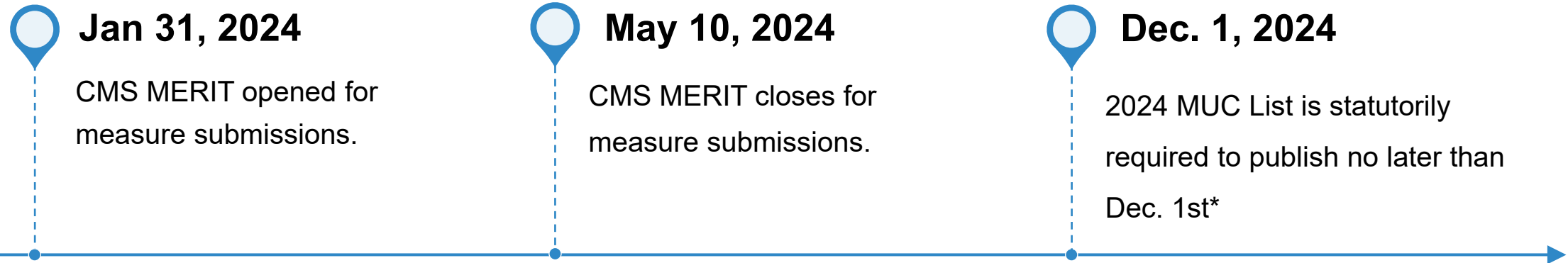
\*Published on the CMS [Measures Management System](#) (MMS) Hub and the [Partnership for Quality Measurement](#) (PQM) Website

# Cyclical Pre-Rulemaking Timeline



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

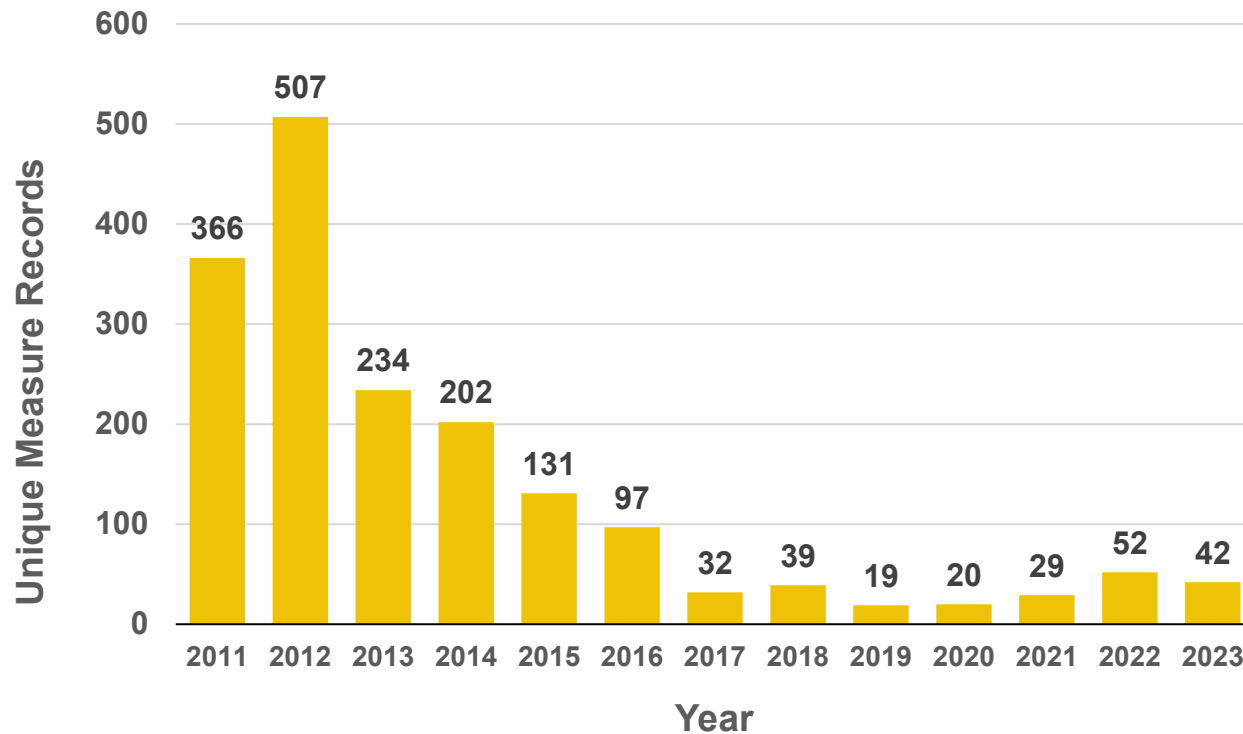
# 2024 Measure Submission Important Dates



\*Published on the CMS [Measures Management System \(MMS\) Hub](#) and the [Partnership for Quality Measurement \(PQM\) website](#).

# 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 \(cms.gov\)](#)

# 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?
- What is the measure's stage of development? Is it fully tested?
- Would the measure be burdensome to operationalize?
- Is the measure endorsed by a consensus-based entity (CBE)?

# 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
- Data Source
- Facility/Setting
- Level of Analysis

# CMS Program Needs and Priorities

- **2024 MUC List Program-Specific Measure Needs and Priorities Report is posted to the [Pre-Rulemaking Resources Webpage on the CMS Measures Management System \(MMS\) Hub](#)**
- **The summary for each program contains the following information:**
  - Program history and structure
  - High priorities for future measure consideration
  - Program-specific measure requirements



# Updates to CMS MERIT



# Measure Submissions

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

About ▾

## Welcome to MERIT!

The Centers for Medicare & Medicaid Services (CMS) MUC Entry/Review Information Tool (MERIT) is the tool for measure developers to submit their clinical quality measures for consideration by CMS.

As part of the CMS Pre-Rulemaking process for programs under Section 3014 of the Affordable Care Act, the Department of Health and Human Services (DHHS) must annually issue a Measures under Consideration List (MUC List) by December 1. Developers submit measures for CMS to consider including in certain CMS programs as required under ACA.

Click [here](#) to learn more about the pre-rulemaking process.

Are you a measure developer in need of a MERIT account? Click "Request an Account" at right.

Note that it may take 24 hours to process your account request. In the meantime, you may review the [MUC List template](#) for information about the fields to complete in MERIT and the [Quick Start Guide](#) to help orient you to the tool.

## Login to MERIT

Username

Password

Token Code

[Forgot your Password?](#) [Request an Account](#)

### Rules of Behavior and Terms of Use

This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to this network or to a computer on this network.

- 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 31st for the 2024 cycle and **will close on May 10, 2024, at 8pm ET.**

# 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



## **Improved Copy and Paste Functionality**

Ability to copy and paste from Word doc



## **Ability to print .pdf of submissions**

Ability to print and save a copy of submission(s) in PDF

# Updates to CMS MERIT for 2024

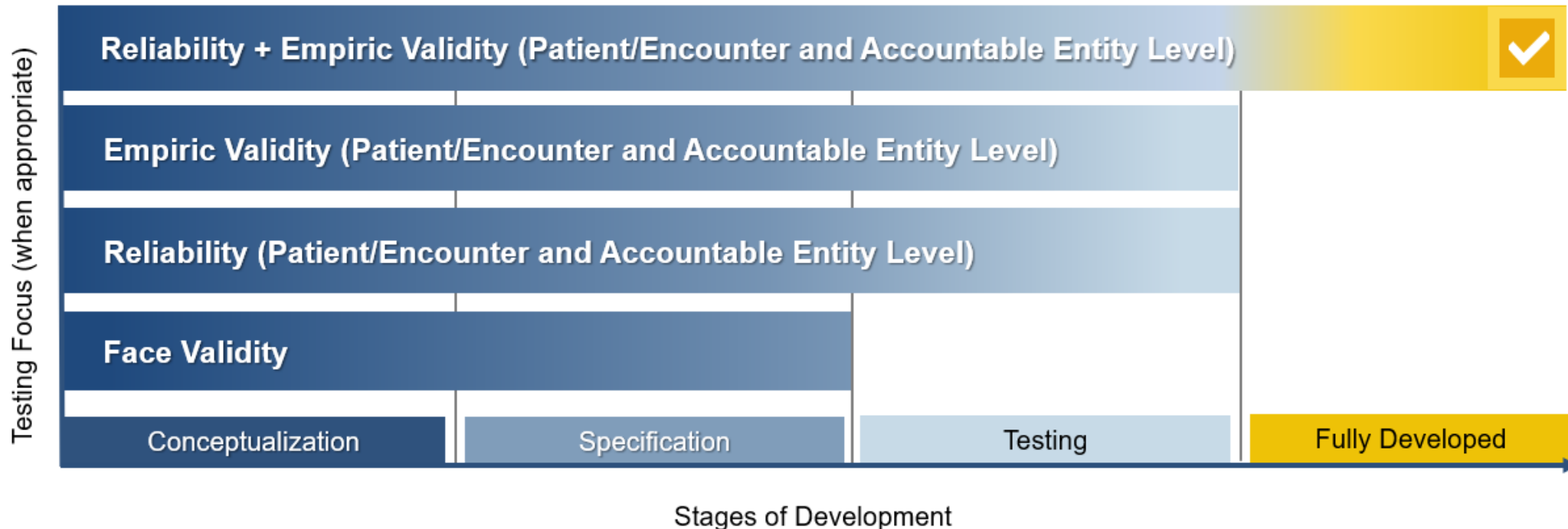
- CMS MERIT is the tool measure developers use to submit measures for consideration by CMS.
  - In 2024, there are **fewer** required fields to complete.
  - Background questions have been updated to refer to the new Pre-Rulemaking Measure Review (PRMR) process (formerly the Measure Applications Partnership [MAP]).
  - New required question to capture whether patient surveys and tools used in quality measures have been translated and validated in Spanish
  - Revised stage of development question asks submitters to indicate **completed** stages of development

# Updates to CMS MERIT for 2024: 508-Compliant Attachments

- CMS requests attachments to be 508-compliant when submitted to CMS MERIT
  - Attachments are made public to improve transparency
  - Being 508-compliant allows for more meaningful feedback
- **Resources:**
  - **Section 508.gov:** <https://www.section508.gov/>
  - **CMS Creating Accessible Products:** <https://www.cms.gov/data-research/cms-information-technology/section-508/public/creating-accessible-products>
  - **HHS Accessibility & Section 508 Policy:** <https://www.hhs.gov/web/section-508/accessibility-checklists/index.html>

# Stage of Development

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



# Required Data Fields

## Key Goals for 2024 Updates:

- Support CMS in addressing the U.S. Government Accountability Office recommendations<sup>1</sup> relative to systematic measure assessment aligned with CMS quality objectives
- Align with CBE criteria<sup>2</sup> and MMS Blueprint Content<sup>3</sup> where feasible
- Reduce measure developer burden and improve flow
- Streamline the collection of measure data

<sup>1</sup> US 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>

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

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

# Required Data Fields

## Refinements for 2024:

### Key Refinements Made to Data Fields:

- Reduced number of MERIT data fields by 30
- Enhanced guidance to clarify submission requirements
- Updated to capture all completed stages of measure development
- Updated various data fields (e.g., *Meaningful to Patients*, *Input from Measured Entities*, and *Measure Data Sources*)
- Streamlined *Evidence* section

# Required Data Fields: Example

- Click “View Definition” to access additional guidance clarifying submission requirements

**Completed Stage(s) of Development \***

[View Definition](#)

**Definition** ✕

Select all stages of development that have been completed. There are five stages in the Measure Lifecycle: conceptualization; specification; testing; implementation; and use, continuing evaluation, and maintenance. Measure conceptualization is the first stage; however, the stages are not necessarily sequential. Instead, the stages are iterative and can occur concurrently.

Select / Unselect All

Measure Conceptualization       Measure Specification       Measure Testing

Measure Use, Continuing Evaluation & Maintenance

Please click [here](#) for guidance on determining whether your measure has completed measure testing.



# Required Data Fields: Example

*Meaningful to Patients* field updated to capture majority agreement

<p><b>Meaningful to Patients. Did the majority of patients/caregivers consulted agree that the measure is meaningful and/or produces information that is valuable to them in making their care decisions? *</b></p> <p><a href="#">View Definition</a></p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not evaluated</p>
<p><b>Description of input collected from patients/caregivers consulted *</b></p> <p><a href="#">View Definition</a></p>	<div style="border: 1px solid #ccc; height: 150px;"></div>
<p><b>Description of input collected from measured entities (Optional)</b></p> <p><a href="#">View Definition</a></p>	<div style="border: 1px solid #ccc; height: 150px;"></div>

# Required Data Fields: Example

Reduced to two data fields for most types of evidence (one free text field and one discrete field)

<b>Type of evidence to support the measure *</b> <a href="#">View Definition</a>	<input type="checkbox"/> Select / Unselect All		
	<input type="checkbox"/> Clinical Guidelines or USPSTF (U.S. Preventive Services Task Force) Guidelines	<input checked="" type="checkbox"/> Peer-Reviewed Systematic Review	<input type="checkbox"/> Peer-Reviewed Original Research
	<input type="checkbox"/> Empirical data	<input type="checkbox"/> Grey Literature	
<b>Briefly summarize the peer-reviewed systematic review(s) that inform this measure concept *</b> <a href="#">View Definition</a>	<div style="border: 1px solid #ccc; height: 100px;"></div>		
<b>Peer-reviewed systematic review citation *</b> <a href="#">View Definition</a>	<input type="checkbox"/> Citation (enter here):	<input type="checkbox"/> URL (enter here):	<input type="checkbox"/> DOI (enter here):
	<input type="checkbox"/> Not available		



# eCQM Readiness

# eCQM Readiness, Step 1: Specification

- **Measure Authoring Tool (MAT) output** to include Health Quality Measure Format (HQMF) human readable files
- **Bonnie test cases** achieving 100% passing and 100% coverage
- **Value sets** published in the Value Set Authority Center (VSAC)
- (optional) eCQM Fast Healthcare Interoperability Resources (**FHIR**) **specification** MAT or Measure Authoring Development Integrated Environment (MADiE) output and test cases

# eCQM Readiness, Step 2: Testing

- Reliability and validity testing that meets the definition of a fully 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 the MAT, Bonnie, MADiE, and VSAC
  - Participate in the eCQM Annual Update process, which is distinct from update cycles for other collection types and may begin at 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
  - Support response to interested party's questions on the measure throughout the year

# eCQM Readiness: Notes and Resources

- MAT and Bonnie will no longer be accessible after June 28, 2024. Measure stewards need to migrate all eCQMs, libraries, and test cases to MADiE prior to this date.
- 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/>
  - MAT: <https://www.emeasuretool.cms.gov/>
  - Bonnie: <https://bonnie.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/>

# CMS MERIT Support



**Quick Start Guide**  
and **2024 MERIT Data**  
**Template** are available  
for download on log in  
[page](#)



**CMS MERIT Tips &**  
**Tricks Session**  
**April 16**  
**12:00 PM Eastern**

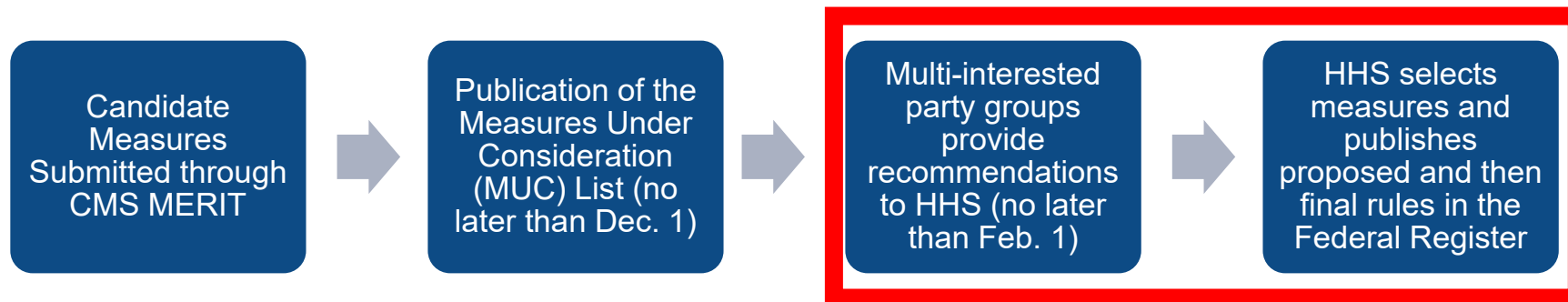


**Contact [MMSsupport@battelle.org](mailto:MMSsupport@battelle.org)**  
with CMS MERIT questions



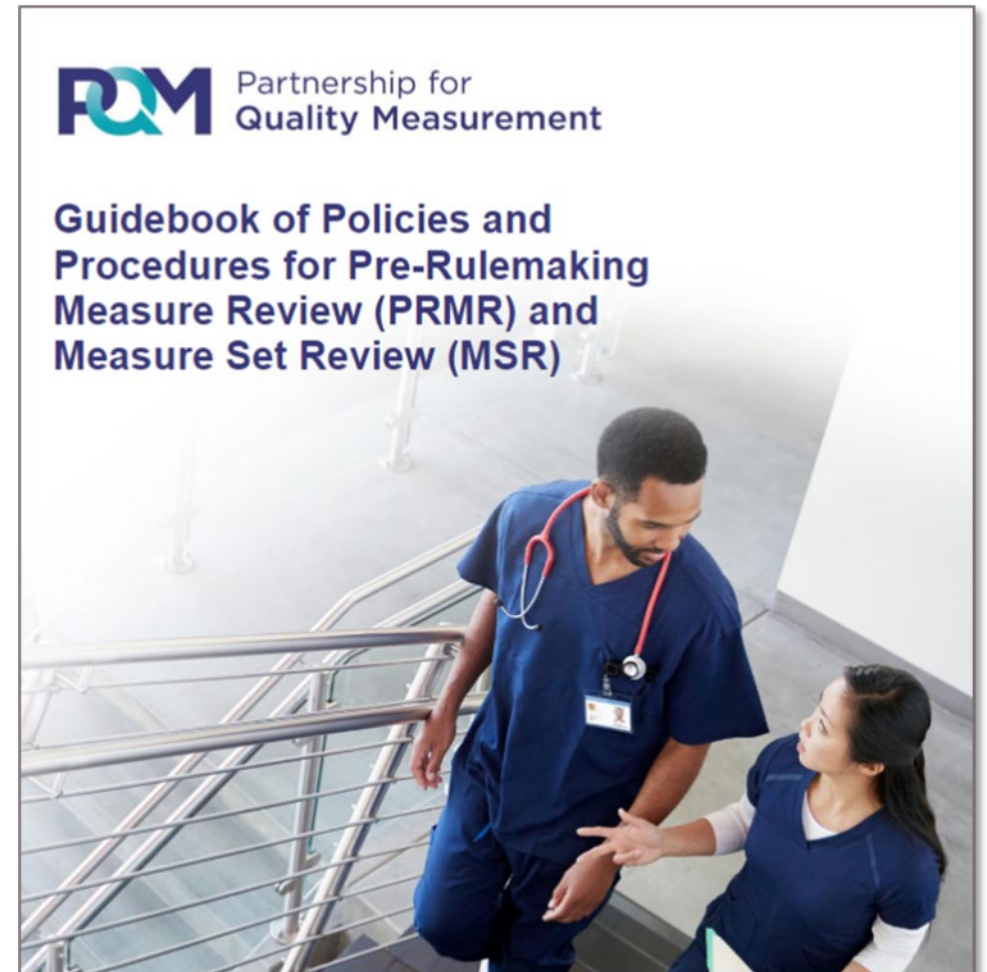
# Pre-Rulemaking Process: PRMR

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 removal criteria

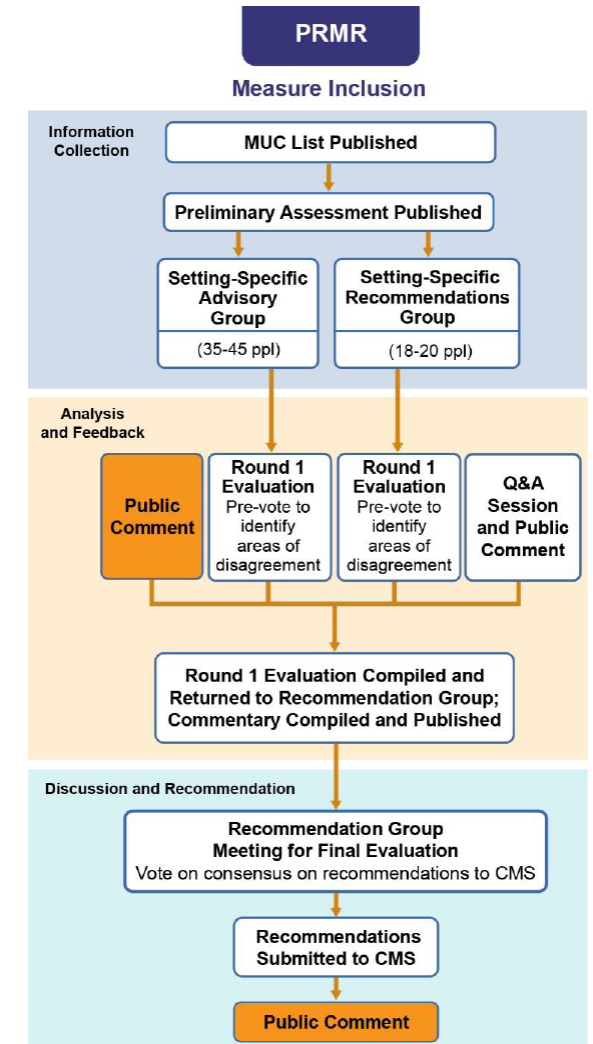


# PRMR Process

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

- **Meetings**

- **Preliminary Analyses: Mid-November**
- **Listening Sessions: Mid-December**
- **Recommendation Meetings: Mid-/Late-January**

- **Non-Meeting Opportunities**

- **Additional Information: August / September**
- **Review Preliminary Analyses: Mid-November**

# Pre-Rulemaking Resources

## Tour of Pre-Rulemaking Webpage

[Pre-Rulemaking | The Measures Management System \(cms.gov\)](#)

CMS.gov | Measures Management System (MMS)

About Quality Measurement | **Blueprint Measure Lifecycle** | Tools & Resources | Get Involved

Home / Measure Implementation

### Measure Implementation

Overview | **Measure Selection** | **Pre-Rulemaking** | Measure Rollout

#### Pre-Rulemaking

Section 3014 of the [Patient Protection and Affordable Care Act](#) (PDF) of 2010 (ACA) (P.L. 111-148) created section 1890A of the Social Security Act (the 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. Section 1890(b)(7)(B) of the Act describes the categories of measures.

[CMS Measures Under Consideration Entry/Review Information Tool \(MERIT\)](#) →

**RESOURCES**

- [Additional Pre-Rulemaking Resources](#) →
- [2022 MUC List Overview \(PDF\)](#) →
- [2022 MUC List \(XLSX\)](#) →

The pre-rulemaking process includes five major steps:

1. Each year CMS invites the submission of candidate measures from measure developers/stewards. The submission period closes on a prescribed date to allow HHS time to review and make their selection of measures to place on the [Measures Under Consideration \(MUC\) List](#).
2. Annually, no later than December 1, HHS makes publicly available a list of quality and efficiency measures that HHS is considering adopting, through the federal rulemaking process, for use in Medicare program(s).
3. Multi-stakeholder groups provide recommendations to HHS no later

# Poll

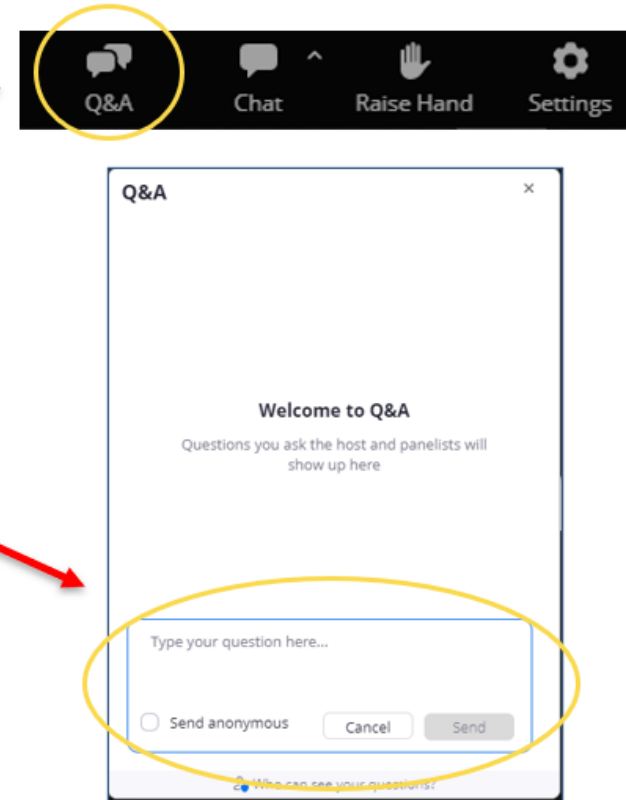
**We want your feedback!**  
Please complete the poll  
to let us know how we're  
doing.



# Questions

Open the Zoom Q&A function

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





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