Pre-Rulemaking: Section 3014 of the Affordable Care Act of 2010 (ACA) (P.L. 111-148) requires that the U.S. Department of Health and Human Services (HHS) establish a federal pre-rulemaking process for the selection of quality and efficiency measures for use by HHS. This process occurs annually and results in the publication of the Measures Under Consideration (MUC) List, which is a list of measures that can be proposed into various Medicare payment and performance programs.

Pre-Rulemaking and Measures Under Consideration 2023 Frequently Asked Questions

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Overview

The purpose of this document is to provide stakeholder guidance related to the pre-rulemaking processes. These processes are a result of the Patient Protection and Affordable Care Act (ACA) of 2010. CMS's goal is to be transparent providing interested audiences and stakeholders with information that enhances CMS's ability to meet its quality and efficiency measurement goals.

After the publication of the MUC List, the consensus-based entity convenes a multi-stakeholder group to provide recommendations to HHS no later than February 1 annually on the quality and efficiency measures under consideration. HHS considers the multi-stakeholder groups' input in selecting candidate quality and efficiency measures.

CMS considers this document to be a "living" source of pre-rulemaking information. Since the first MUC List in 2011, CMS has learned through experience the nuances of pre-rulemaking, the condensed timeline, overlapping rulemaking program calendars, and overcoming the challenges of the federal clearance process to ensure that pre-rulemaking statutory requirements are met. Pre-rulemaking is designed to improve health outcomes and healthcare quality by assisting with the selection of measures. The selected measures produce publicly reported performance results for transparency and healthcare decision-making. The goal of CMS is to align payment with value and rewarding providers and professionals for using health information technology (health IT) to improve patient care.

The following frequently asked questions (FAQs) relate to pre-rulemaking and have been sorted into the categories of Measures Under Consideration Events and Submitting Measures. The document's intended audience is federal HHS agencies, organizations contracted with these federal agencies, and healthcare advocacy groups. For additional information and resources go to the CMS Pre-Rulemaking website.

Measures Under Consideration Events

For the **2023 Measures Under Consideration cycle**, CMS will hold a kick-off webinar to be announced widely by email and on the CMS Pre-Rulemaking website. The intended audiences are federal HHS agencies, organizations contracted with these federal agencies, and healthcare advocacy groups. The topics will include the statute, CMS's quality strategy, highlights of the prior year's lessons learned, pre-rulemaking federal program-specific needs and priorities, as well as the current cycle's milestone dates.

How do I submit candidate measures for the 2023 MUC cycle? The CMS Measures Under Consideration Entry/Review Information Tool (CMS MERIT) is the web-based data collection portal that allows measure developers to submit their clinical quality measures for consideration by CMS.

When can I start submitting candidate measures to CMS through CMS MERIT? The submission period for new candidate measure submissions and comments will open on January 30, 2023.

What is the deadline to submit candidate measures through CMS MERIT? All measures must be completed and submitted by Friday, May 19, 2023. This includes submission of testing information and, if applicable, required MIPS documentation.

What should I do if I want to be invited to meetings about pre-rulemaking and receive pre-rulemaking announcements? Contact MMSsupport@battelle.org to be added to the CMS Pre-Rulemaking mailing list for e-mail announcements and invitations. This is also the support address for general measures management inquiries.

Submitting Measures

For the 2023 Measures Under Consideration cycle, candidate measures, along with any required additional documentation, should be submitted via CMS MERIT.

What are some general submission guidelines for deciding the kinds of measures to submit? In an effort to provide a more meaningful List, CMS prefers to include measures that are fully developed, allowing for meaningful review.

- If CMS chooses not to adopt a measure from the Measures under Consideration List for the current rulemaking cycle, the measure remains under consideration by the Secretary and may be proposed and adopted in subsequent rulemaking cycles.

- Existing measures that are eligible for expansion into different CMS programs should be submitted on subsequent Measures under Consideration Lists.

- Measures may be mandatory or optional.

- Measures appearing on the Measures under Consideration List may or may not be adopted by CMS and implemented in the field. All measures included on the Measures under Consideration List are subject to CMS's rulemaking process.

- A measure can be submitted via CMS MERIT if it was previously submitted to be on a prior year's Measures Under Consideration List but was not accepted by any CMS program(s); it is assumed that the measure will have undergone further development or modification/refinement since the previous submission.

- Measure specifications may change over time. If a measure has significantly changed, it may be submitted for a subsequent Measures Under Consideration List.

Can I submit the same measure for more than one CMS program? Yes, candidate measures can be submitted to more than one program. If the programs use different levels of analysis (ex. clinician, facility, health plan), the submitter will need to make multiple submissions. Due to the specificity of the information gathered during the submission process, each level of analysis requires individual submission. However, if multiple programs use the same level of analysis only one submission is necessary. If your measure is tested at multiple levels, please reach out to MMSSupport@battelle.org for guidance and support. There is functionality within CMS MERIT to decrease the data entry process for multiple submissions of the same measure.

Should the CMS program name be included in the measure title field? The CMS program name should not ordinarily be part of the measure title, because each measure record already has a required field that specifies the CMS program. An exception would be if there are several measures with otherwise identical titles that apply to different programs. In this case, including or imbedding the program identifier at the end of each title (to prevent there being any duplicate titles) is helpful.

If my measure is not ready for submission by the deadline above, when is the next opportunity to submit a measure to CMS? The pre-rulemaking process is annual, and candidate measures will next be accepted starting early the following year.

Will the candidate measure submissions from the current year be implemented and used in the field for the following year? CMS is accepting candidate measures now to develop a Measures Under Consideration List that will be reviewed by a multi-stakeholder group convened by the consensus-based entity to provide recommendations to HHS and to be published by February 1 following release of the Measures under Consideration List in December. Following review of the recommendations, CMS may decide to propose the measure for a program. The program will include the measure in proposed rule, seek public comment, and potentially finalize the measure in the program. Typically, measures are implemented and data is collected for a year or two prior to being used for public reporting or payment determination.

What should I do if I need to modify or remove a candidate measure after the original submission has already been made? See the CMS MERIT Quick Start Guide for Submitters for instructions. Modifications after the submission deadline may not be possible.

Who approves changes made to a measure after submission? CMS reviews and decides on all candidate measure modification requests after the submission deadline.

If a measure is adopted, will the developer be notified personally or does the developer need to go to CMS website? When will this announcement occur for approved measures? The finalized measures for each program are identified in the rule associated with that program. Just because a measure went through the pre-

rulemaking process does not mean that it will be adopted in that particular program through a proposed and final rule.

Where do I find the prior year's Measures Under Consideration (MUC) List? You can find this information on the [CMS Pre-Rulemaking website.](#)

Does CMS offer a measure inventory? CMS's measures inventory has been enhanced over time and is a resource that may be used to help avoid duplication or overlap. Here is the link to the CMS Measures Inventory Tool (CMIT): [https://cmit.cms.gov.](https://cmit.cms.gov)

CMS has emphasized moving toward more Outcome measures and fewer Process measures. How can I tell which Measure Type applies to my candidate measure? Refer to the [CMS Measures Blueprint](#) for further information on how to select the best [measure type](#) for your measure.

If measures are preferred to be fully developed, how are some eligible for review by MUC as "Conceptualization", "Specification", or "Field (Beta) Testing"? Measures with a status of "Conceptualization", "Specification", or "Field (Beta) Testing" tend to be exceptions. For example, a measure may have a status of "Specification" or "Field (Beta) Testing" if Congress requests a measure for inclusion in the MUC list and ultimately to be implemented in a program. These measures still undergo appropriate testing as part of the measure development process. Ideally, measures published in the MUC List are fully developed.

When describing the state of development details, what information is requested? Stage of development details are requested for measures that are in "Conceptualization", "Specification", or "Field (Beta) Testing" stages of development. For measures in these stages of development, use the stage of development details field to describe when testing is planned (i.e., specific dates), what type of testing is planned (e.g., alpha, beta), as well as the types of facilities in which the measure will be tested. For candidate measure submissions in the field testing phase, details are helpful to CMS in understanding where the measure is in the development cycle and will weigh heavily in determining whether or not the measure will be published on the MUC List.

In the "stage of development details" data field guidance, what do the terms "alpha" and "beta" mean? The point of the question is to ascertain the level of readiness of the measure for primetime. Alpha testing is formative testing, and beta testing is field testing. Further information is available in the [CMS Measures Blueprint](#).

What is required if I submit an eCQM? For electronic clinical quality measures (eCQMs), you need to attach the following supporting information to your submission in CMS MERIT:

- Measure Authoring Tool (MAT) Output/Health Quality Measure Format (HQMF)

- CMS Consensus-based entity feasibility scorecard or other quantitative evidence indicating that the measure can be reported by the intended reporting entities

- Bonnie test cases for this measure, with 100% logic coverage

- Attestation that value sets are published in Value Set Authority Center

Would measures without complete MAT/HQMF specification, but in development, be worth submitting? Yes, please submit measures via [CMS MERIT](#) and follow the guidance in the 2023 MERIT Data Template in Word that is available on the [CMS Pre-Rulemaking website](#) and in [CMS MERIT](#).

Can the MAT be used to author any measure, or is the MAT only for authoring electronic clinical quality measures (eCQMs)? Submitters should include MAT numbers for eCQM submissions only. Candidate eCQMs must have a MAT number.

Is the Measure Information Form (MIF) required? No. It is encouraged but not required. If a MIF is not available, comprehensive measure methodology documents are encouraged.

Is the Peer Reviewed Journal Article Requirement Template required? The Peer Reviewed Journal Article Requirement Template applies to all candidate MIPS (Merit-Based Incentive Payment System) measures (both Quality and Cost). The legislation calls for the Secretary of HHS to be responsible for submitting candidate MIPS measures to a peer reviewed journal. The 2023 MIPS Peer-Reviewed Journal Article Template and examples (for eCQMs and non-eCQMs) are available for download in the Resources section of the [CMS Pre-Rulemaking Website.](#) Please also check this section for the 2023 MIPS Annual Call for Measures Fact Sheet.

Can one measure have two or more Healthcare Domains? Each measure should identify at least one Domain, but may recognize other domains as well . For more information, see: https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization

If the measure is reported to CMS via Quality Net, what is the appropriate reporting option to select in CMS MERIT? For the item "How is the measure expected to be reported to the program?" choose "Other." This is the anticipated data submission method. Select all that apply. Use the" Submitter Comments" field to specify or elaborate on the type of reporting data, if needed to define your measure.

For More Information

- Pre-rulemaking Website:

  https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking

- Link to CMS MERIT:

  https://cmsmerit.cms.gov/

- Link to CMS Program Measure Needs and Priorities Report: Click here

- Call for measures Website:

  https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Call-for-Measures.html

- Email MMSsupport@battelle.org for additional information