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: The Measure Submission Period and the Measures Under Consideration (MUC) List - 2025 Frequently Asked Questions

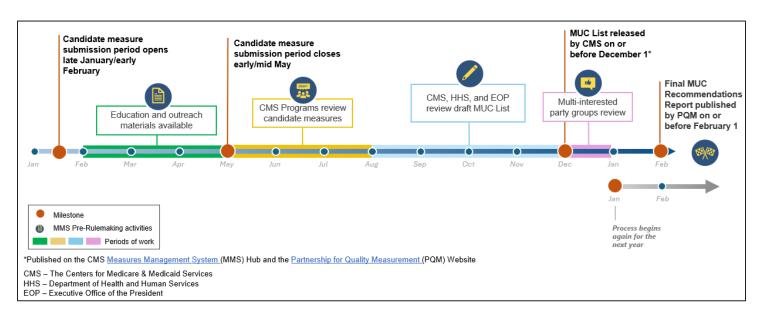
Table of Contents

Overview <u>Pre-Rulemaking Events</u> <u>Submitting Measures via CMS MERIT</u> <u>For More Information</u>

Current as of February 2025

Overview

This Frequently Asked Questions (FAQ) document addresses the pre-rulemaking process, as established by the Affordable Care Act of 2010. This process allows the Centers for Medicare & Medicaid Services (CMS) to transparently share and gather public input on potential measures for payment and performance programs. This initiative aims to enhance healthcare quality and efficiency, support informed decision-making, and promote the use of health information technology to improve patient care.



Pre-rulemaking follows a similar timeline year to year as shown in the graphic below:

The following FAQs relate to pre-rulemaking and have been sorted into the categories of Pre-Rulemaking Events and Submitting Measures via CMS Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT). The document's intended audience is federal HHS agencies, organizations contracted with these federal agencies, measure developers, health care advocacy groups, and anyone interested in CMS quality measures. CMS considers this document to be a "living" source of pre-rulemaking information. For additional information and resources go to the <u>Pre-Rulemaking Webpage on the CMS Measures Management System (MMS) Hub.</u>

Pre-Rulemaking Events

For the **2025 Pre-Rulemaking Cycle**, CMS will hold a public Pre-Rulemaking webinar during the measure submission period. This webinar will be announced widely by email and on the <u>MMS Hub</u>. The intended audience is federal HHS agencies, organizations contracted with these federal agencies, measure developers, health care advocacy groups, and anyone interested in CMS quality measures. The topic of the webinar will include the statute, pre-rulemaking federal program-specific needs and priorities, as well as the current cycle's milestone dates. In addition, a CMS Measures Under Consideration Entry/Review Information Tool (MERIT) Tips & Tricks webinar will be held prior to the close of the measure submission period. The webinar will focus on the tips and best practices for navigating CMS MERIT and submitting measures via the online portal. Recordings for all events will be posted to the <u>Pre-Rulemaking Resources</u> page on the <u>MMS Hub</u>.

What should I do if I want to be invited to meetings about pre-rulemaking and receive prerulemaking announcements? Contact <u>MMSsupport@battelle.org</u> 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.

How do I get more involved with the multi-interested party group that provides recommendations to CMS (known as Pre-Rulemaking Measure Review (PRMR) committees) once the MUC List has been published (i.e., after December 1)? The consensus-based entity convenes multi-interested party groups to provide recommendations to CMS no later than February 1 annually on the quality and efficiency measures under consideration. CMS considers the multiinterested party groups' input in adopting candidate quality and efficiency measures for use in a Medicare program. For more information on this process, please visit the <u>Partnership for Quality</u> <u>Measurement (PQM) Pre-Rulemaking Measure Review (PRMR</u>) Website.



Submitting Measures via CMS MERIT

How and when can I submit candidate measures for the 2025 Pre-Rulemaking cycle? The CMS Measures Under Consideration Entry/Review Information Tool (<u>CMS MERIT</u>) is the web-based data collection portal that allows measure developers to submit their clinical quality measures for consideration by CMS. The submission period for new candidate measures opens annually in late January/early February.

What is the deadline to submit candidate measures through CMS MERIT? All measures must be completed and submitted by 8:00PM ET on Thursday, May 1, 2025. This includes submission of testing information and, if applicable, required Merit-based Incentive Payment System (MIPS) documentation.

What are some general submission guidelines for deciding the kinds of measures to

submit? In an effort to provide a more meaningful MUC List, CMS prefers to include measures that are fully tested, allowing for thorough review.

- If CMS chooses not to adopt a measure from the MUC 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 MUC Lists.
- Measures may be mandatory or optional for the quality program to which they are being submitted.
- Measures appearing on the MUC List may or may not be adopted by CMS and implemented in the field. All measures included on the MUC List are subject to CMS's rulemaking process.
- A measure can be submitted via <u>CMS MERIT</u> if it was previously submitted to be on a prior year's MUC 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 substantively changed, it may be submitted for a subsequent MUC List.

 Measures should address program needs and priorities (see the Needs and Priorities Report on the <u>Pre-Rulemaking Resources</u> page on the <u>MMS Hub</u> for details).

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 <u>MMSSupport@battelle.org</u> 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 embedding 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. Measure submitters should stay tuned for announcements about when MERIT will open for the next season. Typically, MERIT opens in late January/early February.

If a measure is submitted without complete testing results, what is the process for providing testing updates to the MUC submission? Measure submitters should submit their most up to date and complete measure testing results prior to the closing of CMS MERIT by 8:00 PM ET on Thursday, May 1, 2025. There is no option for submitters to submit late measure testing information in CMS MERIT once the submission period has closed. Updated testing data for select measures will be requested by CMS in the fall in preparation for multi-interested party review. For more

information on the multi-interested party review, please visit the Partnership for Quality Measurement (PQM) <u>Pre-Rulemaking Measure Review (PRMR) Website.</u>

Will the candidate measure submissions from the current year be implemented and used in the field for the following year? CMS is currently accepting candidate measure submissions for CMS review to develop the MUC List, though not all submitted measures will be accepted. Once published by December 1, this list will be reviewed by a multi-interested party group convened by the CMS contracted consensus-based entity, which will provide recommendations to CMS. The final recommendations report will be published by February 1. 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.

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

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

Where do I find the prior year's Measures Under Consideration (MUC) List? You can find this information on the <u>Pre-Rulemaking webpage on the CMS MMS Hub.</u>

Does CMS have a measures inventory? <u>CMS's Measures Inventory Tool (CMIT)</u> has been enhanced over time and is a resource that may be used to help avoid duplication or overlap.

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 <u>CMS MMS</u> <u>Hub</u> for further information on how to select the best <u>measure type</u> for your measure.

Current as of February 2025

If measures are preferred to be fully tested, how are some measures eligible for review by CMS as in the stages of "Measure Conceptualization", "Measure Specification", or "Measure Testing"? Measures with a status of "Measure Conceptualization", "Measure Specification", or "Measure Testing" tend to be exceptions. For example, a measure may have a status of "Measure Specification" or "Measure 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 tested.

When describing Completed Stages of Development details, what information is requested?

There are five stages in the <u>Measure Lifecycle</u>: 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. For candidate measure submissions, select all stages of development that have been completed. This information is helpful to CMS in understanding where the measure is in the development cycle and will weigh heavily in determining whether 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 implementation. Alpha testing is formative testing, and beta testing is field testing. Further information is available on the <u>CMS MMS Hub</u>.



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 Development Integrated Environment (MADiE) 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
- Test cases exported from MADiE, with 100% coverage/100% passing both QRDA and Excel format
- Attestation that value sets are published in Value Set Authority Center

Would measures without complete MADiE/HQMF specification, but in development, be worth submitting? Yes, please submit measures via <u>CMS MERIT</u> and follow the guidance in the 2025 MERIT Data Template in Word that is available on the <u>Pre-Rulemaking Webpage on the MMS Hub</u> and in <u>CMS MERIT</u>.

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

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. A MIF template can be downloaded from the <u>MMS Hub.</u>

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) only. The legislation calls for the Secretary of HHS to be responsible for submitting candidate MIPS measures to a peer reviewed journal. The 2025 MIPS Peer-Reviewed Journal Article Template and examples (for eCQMs and non-eCQMs) are available for download in the Resources section of the <u>Pre-Rulemaking Webpage on the MMS Hub.</u> Please also check this section for the 2025 MIPS Annual Call for Measures Fact Sheet.

Can one measure have two or more Meaningful Measures 2.0 priorities?? Each measure should identify at least one priority, but may recognize other priorities as well. For more information, please visit the <u>Meaningful Measures 2.0</u> page.

If the measure is reported to CMS via QualityNet, 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" and enter "QualityNet" in the "enter here" space.

For More Information

- <u>MMS Hub</u>
- Pre-Rulemaking Webpage on MMS Hub
- <u>Pre-Rulemaking Resources on MMS Hub</u>
- <u>CMS MERIT</u>
- <u>CMS Program Measure Needs and Priorities Report</u>
- Visit the Partnership for Quality Measurement (PQM) <u>Pre-Rulemaking Measure</u> <u>Review (PRMR) Website</u> to learn about interested-party review occurring after publication of the MUC List
- Email <u>MMSsupport@battelle.org</u> for additional information



