

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 2021 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. As a result of the legislation, in 2011, CMS published the first Measures Under Consideration (MUC) List for the Department of Health and Human Services (HHS) by December 1. Each year no later than December 1, CMS is statutorily required to publish an annual List.

The current HHS contracted consensus-based entity (the National Quality Forum [NQF] Measure Applications Partnership [MAP]), convenes each winter to fulfill its statutory requirement of providing input to HHS on measures under consideration for use in CMS's federal programs. These federal programs are named explicitly in the Act. The MAP consists of several workgroups including: Clinicians, PAC/LTC (Post-Acute Care/Long-Term Care), Hospitals, Rural Health, and the Coordinating Committee.

Annually, each December and January, the MAP workgroups and the Coordinating Committee meet to provide program-specific recommendations to HHS by February 1 with the first report published and submitted to HHS on February 1, 2012, and then each year thereafter.

CMS considers this document to be a “living” source of pre-rulemaking information. Since the first MUC/MAP cycle in 2011, CMS has learned through experience the nuances of pre-rulemaking, the condensed time-line, 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 that produce publicly reported performance results for transparency and healthcare decision-making, aligning 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 following categories: Measures Under Consideration Events, Submitting Measures, and Measure Applications Partnership (MAP). 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 website at the following link: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html>

Measures Under Consideration Events

For the **2021 Measures Under Consideration cycle**, CMS will hold webinars 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 2021 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 MERIT? The submission period for new candidate measure submissions and comments is to open on January 29, 2021.

What is the deadline to submit candidate measures through MERIT? All measures must be completed and submitted by Thursday, May 27, 2021. This includes submission of testing information and, if applicable, required MIPS documentation.

What is the purpose of the federal-only stakeholder meeting? The **federal-only** stakeholder meeting normally concludes CMS's Measures under Consideration List review process, which officially kicks-off the federal HHS agencies' clearance review and approval process for the Measures under Consideration List.

During the federal-only meeting, agency representatives from across HHS will be briefed by each CMS program and measure lead regarding the submitted measures under consideration for the current cycle. CMS measure and program leads will convey how the candidate measures meet CMS's program needs and priorities. In preparation for the meeting, the specifications of candidate measures will be provided to the HHS federal agencies. To effectuate a seamless, smooth clearance process, CMS requests that federal HHS agency representatives responsible for clearance review and approval be present and be prepared with concurrence or objections for each of the candidate measures. The meeting objective is for CMS staff to address all questions and concerns related to the Measures Under Consideration List with the ultimate goal of avoiding any objections and concerns to proposed measures after this August meeting, and to prevent changes to the Measures Under Consideration List once in clearance. Clearance is scheduled to begin in September.

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 2021 Measures Under Consideration cycle, candidate measures, along with any required additional documentation, should be submitted via [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 will include only measures that 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.

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 collecting measures now that will be reviewed by the Measure Applications Partnership in the following November-January timeframe. MAP recommendations will be published by February 1 following release of the Measures under Consideration List in December. In terms of whether or not a measure will be included in a rule, that would be specific to a particular program and whether or not the program decides to adopt a measure for rulemaking, which is a completely separate process. Those calendars vary by 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 [MERIT Quick Start Guide for Submitters](#) for instructions.

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

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 [CMS MERIT](#) as well as 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>

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 must be fully developed, how are some eligible for review by MUC as “Status = Early Development or Field Testing”? Measures with a status of “Early Development or Field Testing” tend to be exceptions. For example, a measure may have a status of “Early Development or Field 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. Typically, all measures must be fully tested to be published on the MUC List.

When describing the state of development details, what information is requested? Summarize results from validity testing including number of reporting entities and patients measured, and how validity was assessed. Summarize results from reliability testing including number of reporting entities and patients measured, and how reliability was assessed. Note that if a measure is fully specified, but still being tested, the submitter should multi-select both fully developed and field testing for “state of development” to demonstrate to CMS that the fully specified measure is still undergoing field testing. 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.

For the “state of development details” data field, what do the options “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 include or attach the following supporting information:

- 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

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- See guidance on the **MUC Template** for more information.

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 Measures Under Consideration List Template in Word that is available on the [CMS Pre-Rulemaking website](#).

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

Can one measure have two or more Healthcare Domains? Each measure must have only one Domain. 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 MERIT? For the item “How is the measure expected to be reported to the program?” choose “Other.” Then use the separate Comments field to indicate the reporting method that applies to your measure.

Measure Applications Partnership (MAP)

When will the MAP workgroup meetings be scheduled? In general, the Measures Under Consideration List is published annually no later than December 1. The MAP workgroup meetings occur from November through December with the Coordinating Committee meeting in January. For more information visit the National Quality Forum's website: <http://www.qualityforum.org/map/>

Who can attend the MAP workgroup meetings and the Coordinating Committee meetings? All MAP meetings are open to the public. For more information visit the National Quality Forum's website below: <http://www.qualityforum.org/map/>

Should a measure developer, submitter, or steward attend the MAP workgroup meeting? Your attendance coupled with your ability to respond to workgroup members' inquiries enable the workgroup members to make an informed decision relative to their vote on each respective candidate measure. CMS recognizes the importance of your attendance to address MAP workgroup inquiries that cannot be addressed by information gleaned from [CMS MERIT](#).

As a measure developer, submitter, or steward, can I attend the MAP workgroup meetings remotely by teleconference or webinar? You have the option of attending these public meetings either in-person or via webinar/teleconference.

For candidate measures appearing on a published Measures under Consideration List and receiving a MAP decision category of "Conditional Support" or "Potential for Mitigation," are these revised measures required to be added to a subsequent Measures under Consideration List? The caveat is a substantive change to the originally submitted measure. Measures receiving a MAP decision category of "Conditional Support" or "Potential for Mitigation" would not need to be resubmitted to the subsequent year's Measures under Consideration cycle. These measures, if going forward into rulemaking, will be brought back to the MAP via the Feedback Loop process. A measure needs to go on the list only once, unless the measure has undergone substantive changes, at which time it will need to be resubmitted.

For More Information

- Pre-rulemaking Website:
<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html>
- 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