2025 Pre-Rulemaking Webinar Transcript

[SLIDE 1]

MODERATOR: Good morning, all. Thank you to everyone for joining us for today's MMS Information Session. We will be talking today about the 2025 pre-rulemaking, and we're going to be talking about navigating this year's submission cycle with confidence.

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[SLIDE 2]

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.

5   3/11/2025

MODERATOR: So, before we get started, we have some housekeeping notes. So all audio lines will be muted during this presentation. The meeting will be recorded, and we will upload the recording to the pre-rulemaking resources webpage on the CMS Measures Management System (MMS) Hub for future viewing. And then we'll also be addressing questions later in the presentation.

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[SLIDE 3]

MODERATOR: So, to ask questions, you'll see on the bottom ribbon in your Zoom window there is the Zoom "Q&A" function. So all you need to do is click on that. You can type your question into the question box and press "send" to submit.

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Agenda

- **Pre-Rulemaking Overview**
- **Updates to CMS Measures Under Consideration Entry/Review Information Tool (MERIT)**
  - What is CMS MERIT?
  - Description of features
  - Updates to CMS MERIT for 2025
  - Guidance on completing required fields
  - eCQM requirement clarifications
- **Pre-Rulemaking Measure Review (PRI**
- **Support & Resources**
  - Tour of Pre-Rulemaking webpage
- **Questions and Answers**   3/11/2025

MODERATOR: So for today's agenda, we're going to be going over and giving a quick overview of pre-rulemaking. And then we'll be providing some updates on the CMS MERIT tool, and so we'll go over the updates for MERIT for 2025. We'll also be discussing the Pre-Rulemaking Measure Review (PRMR) process. We'll provide some support and resources and give a tour of the pre-rulemaking webpage. And then we'll end with a question and answer (Q&A) session. So with that, we are going to hand it over to Mel Gross to get us started.

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GROSS: Thank you. Hello, everyone. My name is Melissa Gross, and I am the CMS task lead for the pre-rulemaking task for things like MERIT submissions and the MUC List. So we're going to be talking about the background of pre-rulemaking, what the timelines look like for this year, and then some key considerations for measure submitters to think about when they're getting ready to submit.

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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

| Candidate Measures submitted through CMS MERIT | Publication of the Measures Under Consideration (MUC) List (no later than Dec. 1) | Multi-interested party groups provide recommendations to HHS (no later than Feb. 1) |

Rulemaking

| HHS selects measures and publishes proposed and then final rules in the Federal Register |
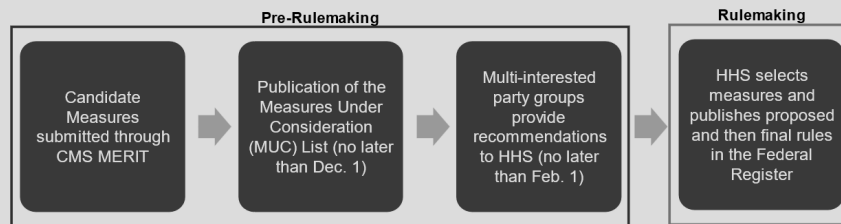
9   3/11/2025

GROSS: So the pre-rulemaking process is a statutorily required process. In Section 3014 of the Patient Protection and Affordable Care Act (PPACA) of 2010, there was a section created called the "1890A of the Social Security Act" which requires 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.

And if you look down on the lower portion of this screen, it goes through the pre-rulemaking process in these boxes. So the candidate measures are submitted through our tool, CMS MERIT. And then the other key points in the pre-rulemaking process are that once those measures are reviewed and recommendations are made for the MUC List, that MUC List will then be published no later than December 1st.

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After that point there is a multi-interested party group that provides recommendations to HHS — no later than February 1st — and that's part of the PRMR process. And then after that, depending on what happens, you know, with the MUC List and if the measure is implemented in a program, it goes through the rulemaking process. So HHS selects measures and publishes proposed and then final rules in the Federal Register, and so there are steps after the pre-rulemaking process.

[SLIDE 7]

Pre-Rulemaking Programs

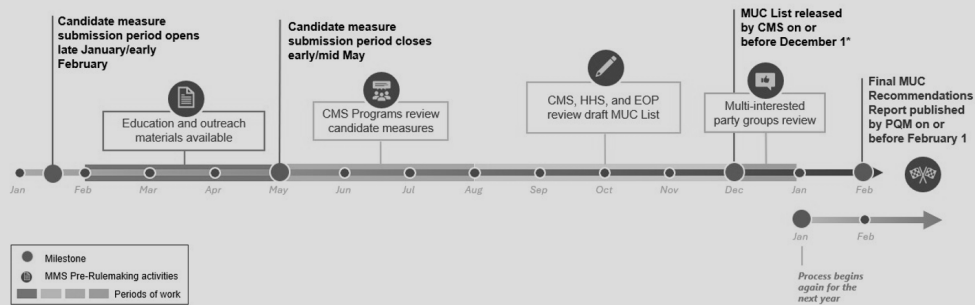The Pre-Rulemaking process for measure selection is used by the following Medicare programs:

- 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

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GROSS: These are the programs that participate in the pre-rulemaking process for measure selection. I won't read through all of these, but these are the participating programs. So you can just look through this for a moment, just to get familiarized.

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GROSS: So we have a couple of timeline slides. This one is a linear timeline. It just makes it easier to see the process, and then we'll show another version of that. So in the end of, or late January-early February, the candidate measure submission period opens, and that means MERIT the tool opens and measure submissions can begin to be submitted.

And then in the background, like today, we are doing education and outreach to make sure that the process is smooth for submitters. So we hold a couple of webinars and Info Sessions to just help that process and get everybody kind of confident in submitting and using the MERIT tool and understanding the process.

In early May the candidate measure submission period closes, and that's when the CMS programs — that the measures have been submitted to — review those candidate measures. That process goes all the way until

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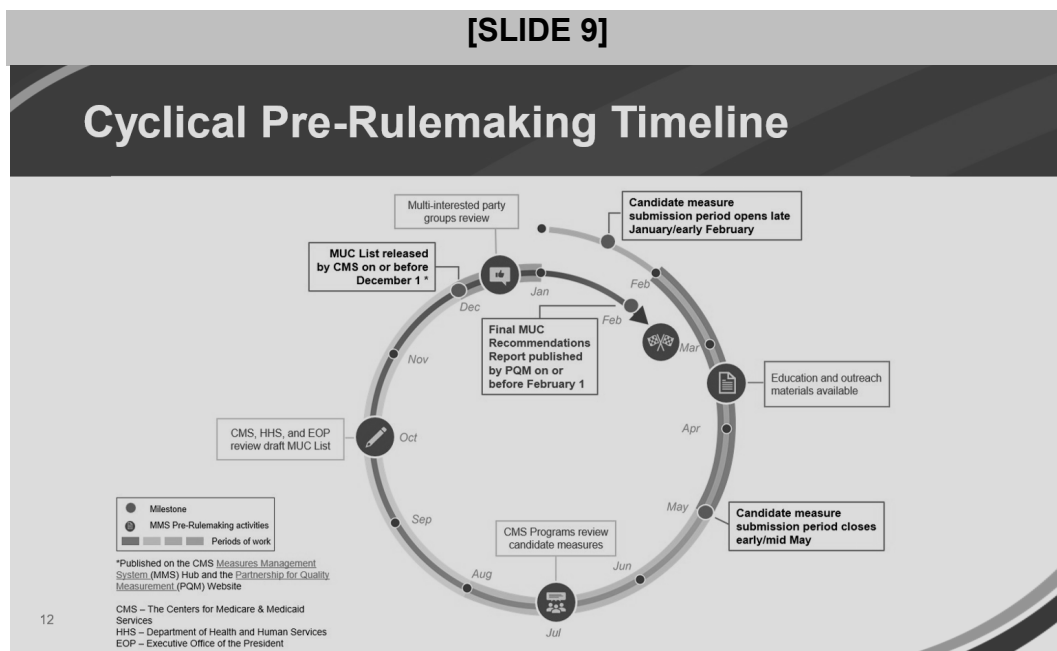*CMS MMS Info Session*:
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early August, or mid-August. And then we go through the clearance process where the MUC List gets reviewed in order to be published. That takes us all the way to December 1. After December 1, the PRMR process and the multi-interested party groups do their reviews, and that leads to the February 1 deadline of the final MUC recommendations being reported to HHS, by Battelle or the PQM. And then again in late January that process starts over again. So I'll just give you a second just to look back over this, just to reorient. And then we're going to go to another slide that just shows the cyclical process of this.

[SLIDE 9]

Cyclical Pre-Rulemaking Timeline

GROSS: So this one is just a representation of the same thing but just showing that as we're closing up and wrapping up that final portion of the MUC List being published — and the PRMR or Pre-Rulemaking Measure Review process is underway — that we are starting the process again the next year for the following cycle.

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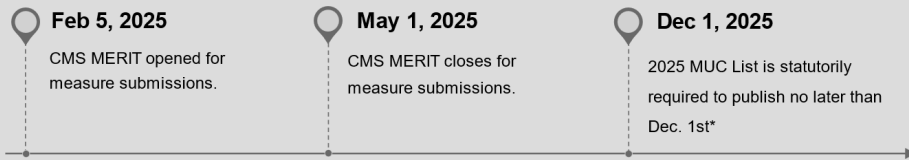*CMS MMS Info Session*:
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[SLIDE 10]

2025 Measure Submission Important Dates

Feb 5, 2025
CMS MERIT opened for measure submissions.

May 1, 2025
CMS MERIT closes for measure submissions.

Dec 1, 2025
2025 MUC List is statutorily required to publish no later than Dec. 1st*

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

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GROSS: So again some key important dates for the submission process. So for this year, for 2025, CMS MERIT opened for measure submissions on February 5th. The closing date for CMS MERIT will be May 1st. And then on December 1st the MUC List, which is statutorily required to be published, will be published before or on December 1st.

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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

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GROSS: Some key measure submission considerations. Measures currently used in CMS programs do not need to go through the MUC List again, except under the following conditions: a measure being expanded into another CMS program, or measures currently used in a program but that underwent substantive changes.

Measure specifications may change over time. If your measure has substantially changed, you should submit it again for consideration. Examples of those substantial changes could include the intent of the measure changes, the facility or setting changes, the data source changes, or the level of analysis changes.

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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?
- Would the measure be burdensome to operationalize?
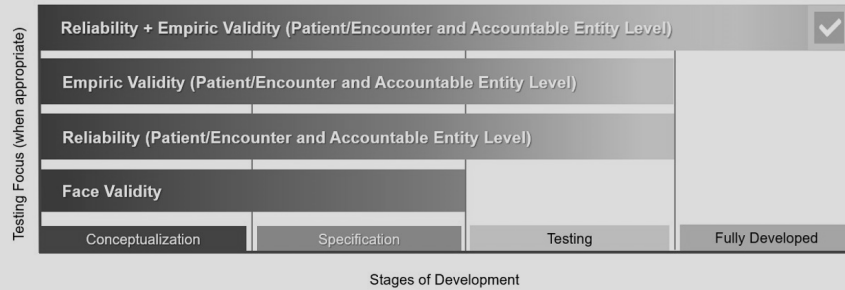- What is the measure's stage of development? Is it fully tested?

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GROSS: So some other key selection considerations that you want to be mindful of is does the submission align with the quality priorities of CMS? Is the submission a digital measure? Is it 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, and if so, could the original measure be removed? Is the measure evidence-based? Would the measure be burdensome to operationalize, and what is the measure's stage of development? Is it fully tested, fully developed?

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Stage of Development

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

Testing Focus (when appropriate)			
Reliability + Empiric Validity (Patient/Encounter and Accountable Entity Level)			☑
Empiric Validity (Patient/Encounter and Accountable Entity Level)			
Reliability (Patient/Encounter and Accountable Entity Level)			
Face Validity			
Conceptualization	Specification	Testing	Fully Developed

Stages of Development

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GROSS: This just shows the stages of development. CMS strongly prefers measures that have been fully conceptualized, specified, and tested. However, with that said, we will evaluate all measures that are submitted at all stages.

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CMS Program Needs and Priorities

- **2025 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

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GROSS: We have a report that we coordinate and update annually. So for the *2025 Program-Specific Measure Needs and Priorities* we've worked with all of the programs to get their updated priorities. This is a good resource for measure submitters to refer to. The information in this report includes the program history and structure, the high priorities for future measure consideration, and the program-specific measure requirements. Some programs have statutory requirements and some do not, but the *Needs and Priorities* kind of outline all of these details for measure submitters to smooth out that process and to know that, you know, you are submitting a measure that's going to be well considered.

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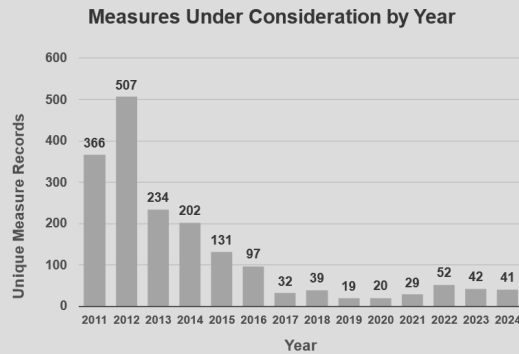*CMS MMS Info Session*:
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MUC List Historical Trends

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)

Year	Unique Measure Records
2011	366
2012	507
2013	234
2014	202
2015	131
2016	97
2017	32
2018	39
2019	19
2020	20
2021	29
2022	52
2023	42
2024	41

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GROSS: We thought it would be important to always share the historical trends of the MUC List over the years. So you can see it's significantly declined over the years, with 2024 having 41 measures on the MUC List. And then you can look at the previous MUC Lists and reports and the pre-rulemaking recommendation reports on the Measures Management System (MMS) webpage.
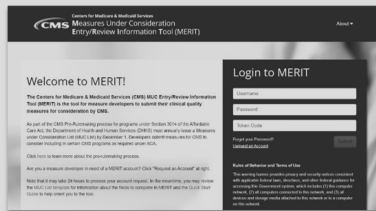
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Updates to CMS MERIT

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GROSS: We hope that you all have a smooth process submitting your measures. What we're going to do next is I'm going to pass it off to Jake at Battelle to specifically discuss the updates that we've made to MERIT to improve the submission process. Over to you, Jake. Thank you.

WEBB: Thank you, Mel. Hello, everyone. As Mel mentioned, my name is Jake Webb. I am the MMS task lead for the pre-rulemaking task. So I just wanted to talk, as Mel mentioned, about some of the updates to CMS MERIT. So every year CMS evaluates the functionality of the MERIT tool to make sure that everything is still in alignment with CMS and other interested parties' needs. So now let's go ahead and take a deep look at MERIT to see what's new for the 2025 pre-rulemaking cycle.

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[SLIDE 17]

What is CMS MERIT?

- 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 CMS MERIT.

- CMS MERIT opened on February 5th for the 2025 cycle and **will close at 8 p.m. ET on May 1, 2025.**

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WEBB: Throughout today's presentation we have mentioned CMS MERIT multiple times. So what is CMS MERIT? The Centers for Medicare & Medicaid Services MUC Entry/Review Information Tool is the tool for measure developers to submit their clinical quality and efficiency measures for consideration by CMS. CMS MERIT, however, is not just a submission tool. By having login access to CMS MERIT, you can also access the "past candidate measures" tab, which is a repository of all the previous submissions. You can filter by year of submissions, programs, measure types, and the status of what was accepted or rejected.

After the measure submission period closes, CMS MERIT will then use the same tool to review those measures. Using CMS MERIT to review the measures enables CMS programs to review measures and communicate with the measure submitters more efficiently, if needed.

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As mentioned earlier in today's presentation, CMS MERIT did open for submissions on February 5th, and it will close 2025 submissions on Thursday, May 1, 2025 at 8:00 pm ET. After this deadline there will be no more submissions. And, if you have not already, I just recommend adding that date to your calendar just to make sure that you have everything you need submitted before that 8:00 pm deadline.

[SLIDE 18]

CMS MERIT Features

CMS MERIT provides features that enhance the efficiency and effectiveness of the submission and review process.

Automatic completeness checks
- CMS MERIT ensures all required measure information is submitted.

Save submissions and return later
- Submitters can save and return later to complete measure information.

Review process tracking
- Submitters and reviewers can track progress of their submission(s).

Easy-to-navigate interface
- Designed with human-centered principles for intuitive and user-friendly navigation.

Copy and Paste Functionality
- Ability to copy and paste from Word docs into submission(s).

Ability to print .pdf of submissions
- Print and/or save a copy of submission(s) in PDF.

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WEBB: CMS MERIT provides numerous features that have enhanced the overall submission and review process. Automatic completeness checks help to ensure that all required measure information has been filled out prior to submission. If you're submitting a measure to CMS MERIT, you don't have to complete a full submission in one sitting. By saving and returning later, you're able to easily work as you can on submitting your measure without feeling rushed. Submitters and reviewers can track the status of the submission to know where it is at every step of the process, and using human-centered design (HCD) principles CMS MERIT has an

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easy-to-navigate interface that helps provide a smooth experience on the tool. CMS MERIT also has improved copy and paste functionality with the ability to be able to copy and paste information from other documents into CMS MERIT. That way if you would like to begin with the Word version of the data template to collaborate within your team, you can now easily copy and paste that information over to the tool.

We do ask that for best results, if you're going to use this feature, to use the "paste" as a plain text to help eliminate any of the hidden formatting that could show up in the system. And then lastly, CMS MERIT also has the ability to print and save a copy of your submission in a PDF format.

[SLIDE 19]

Updates to CMS MERIT for 2025

Steward Information Shifted: Now at the start of the submission process, enabling submitters to input necessary data and include collaborators early on.

Language Updates: MAT and Bonnie language replaced with MADiE language, eCQM submission guidance updated for clearer attachment requirements.

New Proprietary Questions: Asking about proprietary or licensed measure aspects, inclusive of potential licensing fees for CMS or Measured Entities, calling for explanations where needed.

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WEBB: So what's going to be new for CMS MERIT for the 2025 submission cycle? So the first update that you're going to notice is the organizational structure of questions. So both the MERIT data template and the CMS MERIT tool itself follow sections and subsections. So an

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example would be "properties" as being a section and "measure information" being a subsection.

Historically, in the past we have had the "steward" section in the middle of the submission process. New to 2025, you're going to see that that's going to be the first section of questions to answer. We want the submitters to provide this input at the beginning, similar to in school when you would put your name at the top of the paper. It doesn't really make sense for you to have to do it halfway through your work. This is also going to allow submitters to include collaborators to the submission process "earlier" and hopefully be easier to locate.

Throughout the tool you're also going to see some language updates. These updates align with changes that have been made throughout CMS over the last year. You're now going to see MADiE language and guidance where MAT and Bonnie were due to sunsetting of the MAT and Bonnie in the summer of 2024. You'll hear a little bit more about that later. And then within this change you're also going to notice some updated eCQM submission guidance language for attachment requirements.

There's also going to be a few new questions beginning with the 2025 submission cycle. CMS has added questions around if any part of a measure or use of a measure being submitted are "proprietary and/or licensed." If you select "yes," then there is going to be an additional question about licensing fees for either CMS or measured entities, and there's also going to be a field for additional explanation as needed.

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Updates to CMS MERIT for 2025: Composite/Survey Measure Enhancement

- **Previous Process:** Submitters had to enter basic, high -level information into CMS MERIT and attach additional documentation or supplemental materials to the CMS MERIT system for each component or survey -based measure to submission.
- **New Process:** Enables submitters to directly input all necessary information for each component or survey -based measure into CMS MERIT submissions.
- **Benefits:**
    - Streamlines the submission process.
    - Ensures more efficient and comprehensive submissions.
    - Allows submitters to convey measures more effectively to CMS.
    - Facilitates a fuller understanding of the measure by CMS during the review process.

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WEBB: Probably the largest update for the 2025 submission cycle surrounds submissions to composite and survey measures. If you've submitted one of these measures in the past, you're familiar with the process. Historically, submitters have had to enter basic high-level information into the CMS MERIT tool, and then attach supplemental documentation for each of the components for survey-based measures.

We have updated the CMS MERIT tool to now enable submitters to directly input all the necessary information for each component or survey-based measure directly into the CMS MERIT submission. This is going to allow for a more streamlined submission process. Rather than trying to figure out what you need to submit into the tool versus what to add as supplemental — everything will go into this tool. This should also allow submitters to convey measures more effectively to those CMS reviewers.

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**Updates to CMS MERIT for 2025:
Composite/Survey Measure Enhancement Cont.**

Is the measure a composite, survey, and/or a paired measure? * View Definition	☐ Select / Unselect All

☐ Yes, this is a composite measure   ☐ Yes, this is a survey measure   ☐ Yes, this is a paired measure

☐ No, this is not a composite, survey, or a paired measure

If you choose composite or survey, a "Component or Survey-Based Measure" tab will appear at the top of the screen. Navigate to this screen to answer the component and survey-based questions.

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WEBB: So the next couple slides, I just wanted to take a quick moment to talk through and show everyone at a really high level what this new process will look like. So the first step is to identify what your measure is. On this screen you're going to see a screenshot of one of the questions that you'll see in CMS MERIT. This question is asking if a measure is composite, survey, and/or paired. This is not a new question; however, the new functionality of the tool is if you check either "composite" or "survey," it will trigger the system for tabs to appear at the top of the page.

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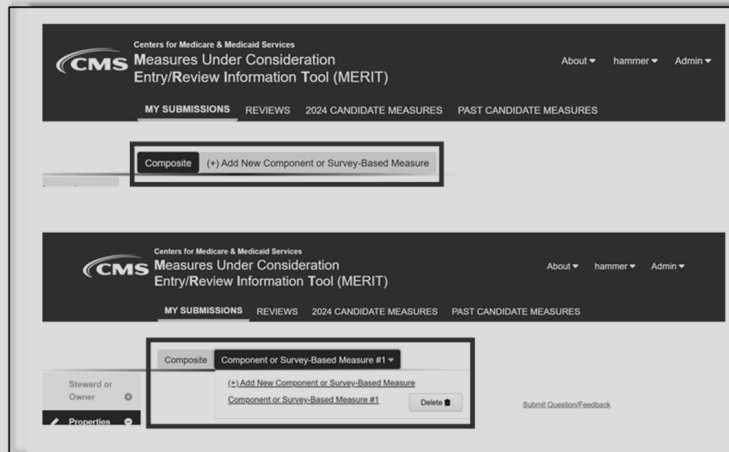*2025 Pre-Rulemaking Webinar:*
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[SLIDE 22]

Updates for 2025:
Composite/Survey Measure Enhancement Cont.

WEBB: The top image is showing a composite tab, and also an "add new component or survey-based measure" tab. The composite tab is where you're going to put all your general measure information, anything that's related to the full measure. You can see in the second image below that you can then add in all the component or survey-based measures your submission would have. This is where you're going to put all the individual information specific to that component or survey-based measure.

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Updates to CMS MERIT for 2025: Composite/Survey Measure Enhancement Cont.

WEBB: And then this slide is just showing you once you add in each of those new components or survey-based measures, what that tool actually looks like. It's going to look almost identical to what is shown in the composite tab or like a normal submission; however, not every field is going to be required for components and survey-based measures. As you can see on the left-hand side, there are some sections and subsections that are greyed out. "Greyed-out" areas indicate that this information is not needed at the component or survey-based measure level and can be pulled from that composite/general measure info tab.

Once you get to this step, the process is very similar as in filling out and submitting. Once you are done with one component or survey-based measure, you will then just repeat that step as many times as you would need. And, as a side note, if you would like to see a live example of a submission of this process, we will be having a Tips & Tricks webinar that

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will be held on Tuesday, April 8th, where I actually will do some live demos of different submissions which will include this. So we will provide that link in the chat here a little bit later in the presentation.

WEBB: If you submitted a measure for consideration last year, this slide may look a little familiar. Section 504 and 508 of the Rehabilitation Act of 1973 helps to ensure that those with disabilities have equal access to government information and communication technology, and thereby to the government employment programs and services which all citizens are entitled. All attachments that are submitted to CMS MERIT are made available to the public to better improve transparency.

Additionally, measures that are accepted to the MUC List have their attachments shared on the MMS Hub, that are then used by the CBE PRMR recommendation committees. So by these attachments being 508

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compliant, this allows for more accessibility to interested parties which then allows for more meaningful feedback.

CMS strongly recommends that all applicable submitted documents be Section 508 compliant prior to the submission of your measures to CMS MERIT. I do want to note that CMS will still consider measures that are submitted to MERIT with attachments that are not 508 compliant. All noncompliant documents will be expected to be remediated in conjunction with the MMS team and the submitter prior to the MUC List being finalized. We have provided some resources that we think are helpful, if you're not fully familiar with that 508 process. So they are in the chat for you. Although, if you have any other questions about this, feel free to reach out to the MMS Battelle@Battelle.org email and we'd be happy to assist.

And with that, I'd like to pass it over to Neil McNinch from Booz Allen to talk about required data fields. Thank you.

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MCNINCH: Thank you, Jake. My name is Neil McNinch and my work supports the evaluation of submitted data.

[SLIDE 26]

Required Data Fields

Key Goals for 2025 Updates:

- Support CMS in addressing the U.S. Government Accountability Office recommendations [1] relative to systematic measure assessment aligned with CMS quality objectives

- Align with CBE criteria [2] and CMS MMS Hub's Blueprint Content [3] where feasible

- Reduce measure developer burden and improve flow

- Streamline the collection of measure data

[1] 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
[2] CBE criteria include pre-rulemaking review (PRMR) and endorsement and maintenance (E&M). https://p4qm.org
[3] https://mmshub.cms.gov/blueprint -measure-lifecycle-overview

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MCNINCH: I would like to take a minute and discuss some changes that have been made to the MERIT required fields. The goal, as always, is to support CMS in satisfying the GAO recommendations for objective assessment of measures and evaluating specifically how they support CMS in achieving its strategic objectives. We also aim to continue aligning with the CBE criteria and MMS *Blueprint* content as much as is possible. Finally, all changes are made with an eye towards reducing measure developer burden by improving flow and clarify wherever possible. To that end, we were able to streamline several questions this year.

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Required Data Fields Cont.

Refinements for 2025:

Key Refinements Made to Data Fields:

- Updated capability to include composite or survey -based measures directly rather than as attachments

- Clarified guidance language (e.g., clarified MIPS testing submission requirements and how to report clinician and/or group level testing)

- Updated selection options (e.g., added "Mixed Logistic Regression" as a Signal -to-Noise reliability testing example, separated "Yes, this is a composite or survey measure" into two distinct options)

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MCNINCH: We were able to make refinements in three main areas. First, to improve clarity and specificity. We created more response options for questions related to composite and survey-based measures, while eliminating the need for attachments. Second, we clarified guidance around how to report clinician and group-level testing, and finally we added specificity to options when entering information related to reliability testing.

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Required Data Fields Example: Is the measure a composite, survey, and/or a paired measure?

Added capability to input data for composite and survey measures directly

Is the measure a composite, survey, and/or a paired measure? *
View Definition

☐ Select / Unselect All

☐ Yes, this is a composite measure   ☐ Yes, this is a survey measure   ☐ Yes, this is a paired measure

☐ No, this is not a composite, survey, or a paired measure

Is the measure a composite, survey, and/or a paired measure? ✕

Select all that apply.

A composite measure contains two or more individual measures, resulting in a single measure and a single score. This includes index measures.

A survey measure refers to a type of performance measure that is derived from data collected through surveys.

Paired measures have different measure scores, but results require them to be reported together to be interpreted appropriately. Note: Individual measures comprising a paired measure must be submitted individually.

If you choose composite or survey, a "Component or Survey-Based Measure" tab will appear at the top of the screen. Navigate to this screen to answer the component and survey-based questions.

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MCNINCH: To give you an example, this is what the composite and survey measure field looks like now. New for 2025 are mutually exclusive options so that you can choose the one most appropriate for your measure. The information box will appear if desired to provide additional information.

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Required Data Fields Example: Level of Analysis

Updated guidance on level of analysis and how to submit Measure Score Level (Accountable Entity Level) testing results if multiple levels are selected

Level of Analysis *
View Definition

Level of Analysis ✕

Select one. Select the level of analysis at which the measure is specified and intended for use. If the measure is specified and intended for use at more than one level, submit the other levels separately. Any testing results provided in subsequent sections of this submission must be conducted at the level of analysis selected here.

For submission to the MIPS-Quality program, you must report, at minimum, the results of individual clinician-level testing.

If testing is performed at both clinician-individual and clinician-group levels of analysis, you may select ?Clinician: Individual and Group.? Please submit results of individual clinician-level testing in this form and group-level testing results in an attachment.

32   For submission to the MIPS-Cost program, clinician group-level testing is sufficient.

☐ Accountable Care Organization
☐ Clinician: Group
☐ Clinician: Individual
☐ Clinician: Individual and Group
☐ Facility
☐ Health Plan
☐ Integrated Delivery System
☐ Medicaid program (e.g., Health Home or 1115)
☐ Population: Community, County or City
☐ Population: Regional and State

MCNINCH: This example for level of analysis, the guidance has been updated and is relevant to any measure that has conducted testing about the individual and group levels. Any testing results provided must be conducted at the level of analysis selected here.

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Required Data Fields Example: Reliability: Type of Analysis

Added Mixed Logistic Regression as an example for Signal-to-Noise reliability testing

	☐ Signal-to-Noise (e.g., Beta-Binomial, Mixed Logistic Regression)	☐ Random Split-Half Correlation
Reliability: Type of analysis * View Definition		

Reliability: Type of analysis ✕

Select all that apply.
Signal-to-noise (or inter-unit reliability) is the precision attributed to an actual construct versus random variation (e.g., ratio of between unit variance to total variance) (Adams J. The reliability of provider profiling: a tutorial. Santa Monica, CA: RAND; 2009. http://www.rand.org/pubs/technical_reports/TR653.html.).
Random split-half correlation is the agreement between two measures of the same concept, using data derived from split samples drawn from the same entity at a single point in time.

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MCNINCH: Finally, signal-to-noise has been updated with examples to provide additional clarity. These are just a few of the many changes we've made to streamline the process. Thank you. I'll turn it over to Joel now.

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eCQM Readiness

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ANDRESS: Good morning, everyone. My name is Joel Andress, and I'm the eCQM lead for the program.

eCQM Readiness, Step 1: Specification

- **Measure Authoring Development Integrated Environment (MADiE) output** to include Health Quality Measure Format (HQMF) human readable files
- **MADiE test case export** achieving 100% passing and 100% coverage
- **Value sets** published in the Value Set Authority Center (VSAC)
- eCQM **Fast Healthcare Interoperability Resources (FHIR) specification** output from MADiE with MADiE test cases included
    - Please note: 2025 is the final year that FHIR specifications will be optional

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ANDRESS: Electronic clinical quality measures (eCQMs) submitted for consideration in CMS programs must be specified using eCQM standards and designated eCQM tools. In addition to completing the fields in MERIT required for all measures, CMS requests the following: 1) MADiE output to show the measure is specified to the latest CMS and ONC standards in a way that aligns with existing eCQMs in CMS programs; 2) MADiE test case exports showing a minimum of 100% passing and 100% coverage of all branches of logic; 3) published value sets in the National Library of Medicine (NLM) Value Set Authority Center or VSAC, that have been validated against the most recent terminology expansion with 100% active codes. Lastly, CMS is advancing the digital transition to Fast Healthcare Interoperability Resources (FHIR).

If the measure steward has already begun specifying the eCQM in FHIR standards, CMS requests the measure steward also submit the FHIR specification MADiE output and test cases. As an important note, 2025 is the final year where QDM eCQMs can be submitted without a FHIR version. 2026 pre-rulemaking submissions will require "both" the QDM and the FHIR specifications of the measure.

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eCQM Readiness, Step 2: Testing

- Reliability and validity testing that meets the definition of a <u>fully developed measure</u>
- <u>Feasibility testing</u> documented on the **feasibility scorecard**

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ANDRESS: The eCQMs submitted for consideration to CMS programs must also meet CMS' definition of a fully developed measure. In addition, measure stewards need to complete and submit a feasibility scorecard for an eCQM. The goal of the scorecard is to illustrate that the data elements required for the measure can be captured in structured fields using data standards within workflow. Similar to the last slide, the bold font here represents the additional information requested in MERIT for eCQMs, that of the feasibility scorecard.

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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 MADiE and VSAC
  - Support responses to interested party's questions on the measure throughout the year

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ANDRESS: Everything covered in eCQM readiness step one and step two relate to work CMS requests to be completed, documented, and submitted for review as part of the Call for Measures for consideration in CMS programs. This slide is intended to provide information on what the measure steward can expect following submission, both in preparation for inclusion in a CMS program and continued maintenance if implemented within a program. A measure steward is expected to understand and apply eCQM standards, including the Quality Data Model (QDM), Clinical Quality Language (CQL) and FHIR. The measure steward is expected to make and test technical changes using eCQM tools, including MADiE and VSAC. Measure stewards are also expected to support responses to interested parties' questions on the measure throughout the year, through our comment tracker.

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eCQM Readiness, Step 3: Steward Expectations, continued

- A measure steward is expected to:
  - Participate in the eCQM Annual Update process, which is distinct from update cycles for other collection types and may begin at a 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
  - Maintain and update value sets used for the measure in VSAC
  - Maintain documents used to support measure updates (e.g., technical release notes, measure flows)

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ANDRESS: A measure steward is likewise expected to participate in the eCQM Annual Update process which is distinct from update cycles for other collection types, that may begin at a different time than other collection types. The steward is expected to adhere to the timelines and processes set forth for the eCQM Annual Update for both QDM-based and FHIR-based specifications. The steward is expected to maintain and update value sets used for the measure in VSAC, and the measure steward is expected to maintain documents used to support measure updates, such as technical release notes, measure flows, and others as required.

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eCQM Readiness: Notes and Resources

- MAT and Bonnie were decommissioned on June 28, 2024. Prior to this date, measure stewards successfully migrated all eCQMs, libraries, and test cases to MADiE.
- 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/
  - 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/

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ANDRESS: CMS would like to use this forum to reiterate two additional considerations for stewards of eCQMs. CMS has decommissioned MAT and Bonnie. These are tools that had previously been used to author and test eCQMs, and they are no longer accessible as of June 28, 2024. All eCQMs have been migrated to the new MADiE tool prior to this date, or prior to that date. More information on this migration is provided in the MADiE resource link on this slide.

CMS is finalizing the path to the digital transformation, and because of that eCQMs in all CMS programs are currently using the Quality Data Model (QDM). As we're transitioning to FHIR, we expect that there will be a period of dually maintaining QDM and FHIR-based specifications to support the future state of all eCQMs being expressed in FHIR. More information on the CMS digital quality measures (dQMs) and FHIR are available on the eCQI Resource Center and the link provided on this slide.

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Thank you for your continued interest and support of eCQMs in the CMS programs, and now I'll turn it over to Kate.

[SLIDE 37]

BUCHANAN: Thank you so much, Joel.

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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** .

Pre-Rulemaking   **PRMR**   **Rulemaking**

| Candidate Measures submitted through CMS MERIT | → | Publication of the Measures Under Consideration (MUC) List (no later than Dec. 1) | → | Multi-interested party groups provide recommendations to HHS (no later than Feb. 1) | → | HHS selects measures and publishes proposed and then final rules in the Federal Register |
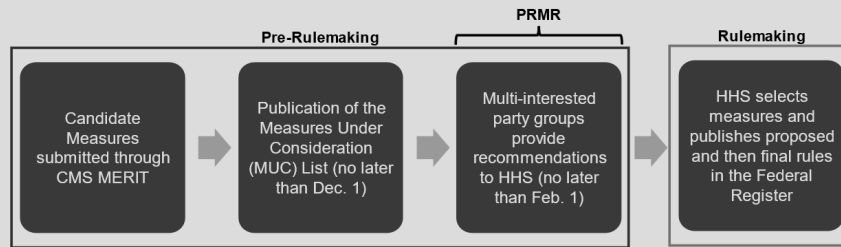
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BUCHANAN: Hi, my name is Kate Buchanan. I'm the deputy task lead of the pre-rulemaking measure review, which we shortened to "PRMR." I'm going to talk through PRMR which is the last stage of the pre-rulemaking process, and this happens after you submit your measures through CMS MERIT and CMS adds your measure to the MUC List.

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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 continued use criteria

PQM Partnership for Quality Measurement

Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review (PRMR) and Measure Set Review (MSR)

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BUCHANAN: As I go through this, I do want to note that our guidebook — which we update and post for public comment annually — has many more details on our process, timelines, committee makeup and evaluation criteria. So if you have additional questions or would like some more detail, a link to the guidebook is in the chat.

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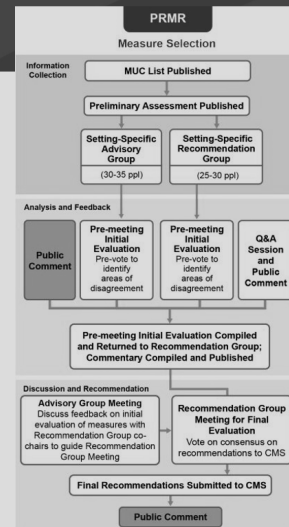March 10, 2025   Page 40

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

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BUCHANAN: So the goal of PRMR is to build consensus on the MUC List measures as to whether they are appropriate for consideration for CMS quality reporting programs (QRPs) and value-based programs (VBPs). This work occurs in three major phases. The first is information collection. During this phase CMS publishes the MUC List. This kicks off our public work where we publish the preliminary assessments, the Battelle status analysis of the measure. Battelle ensures that quality measure developers have an opportunity to review and provide feedback on the PA prior to its release.

And then we go into the second phase, "analysis and feedback." In this phase we gather feedback from members of the public, as well as our committees. We have a written 21-day public comment period. During this written public comment period we also host three listening sessions,

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one per setting, which allows members of the public to provide verbal comment or questions on the measures.

While all of this is happening, our committee members are busy reviewing their assigned measures. They are assigned a subset of all measures assigned to their committee and completing their Pre-Meeting Initial Evaluation forms, which we call "PIE forms." This all culminates in our final phase — discussion and recommendation.

So at the top of the graphic you can see that we have two groups — the advisory group, and the recommendation group. Each committee which we have three — clinician, hospital, post-acute care (PAC) and long-term care (LTC) — is comprised of these two groups. Both groups complete the written PIE analyses. The advisory group meets before the recommendation group and discusses their feedback on the measures. After this Battelle staff compile public comment, listening session comment, PIE form analysis, advisory group feedback, and convenes the recommendation group. The recommendation group considers all of this and votes on measure recommendations for CMS consideration.

At the very end you'll see we have another public comment. This doesn't change the recommendation group final recommendations, but it does allow for additional datapoints for CMS to consider.

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Measure Developer's Role in PRMR

Meeting/Activity	Timeframe	Purpose/Developer Role
Optional submission of updated testing results for measures under consideration	August/September	Ensure PRMR committees have access to updated/final testing information during their reviews
Developer/Steward Education Meeting	October	Review PRMR process, evaluation criteria, and key milestones.
Review Preliminary Analyses	October/November	Ensure accuracy of preliminary analysis of measure information according to PRMR evaluation criteria prior to publication
Listening Sessions	Mid-December	Opportunity for spoken public comment on measures. Measure developers may be invited by CMS leads to respond to questions raised.
Advisory Group Meetings	Early January	Opportunity for (non-voting) Advisory Group members to provide feedback to committee cochairs. Measure developers are invited to listen in as members of the public
Recommendation Group Meeting	Mid-Late January	Discussion and voting to recommend measures for further federal rulemaking. Measure developers may be invited by CMS leads to respond to questions raised.

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BUCHANAN: And then throughout this process we want to engage developers and stewards in every step. So you see here on this chart we have the different topics and different activities that I discussed and how we'll be involving you. So the first is the optional submission of updated testing results for the measures under consideration (MUC). This happens in August and September. The role of this is to ensure that all of the primary committees have access to the most up-to-date information in their reviews. In October we'll convene you all for a developer and steward education meeting. This is to help prepare you for the rest of the process, and to address any questions you may have, and to let you know about key milestones and review your role in this.

Around this time we're also going to ask you to review the preliminary assessment. Now, this is to ensure the accuracy of the measure information according to the PRMR evaluation criteria. Now, we really

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want to ensure that we're all on the same page here, and if you have feedback, we want to incorporate it and ensure that you feel comfortable with what we're posting, and that we feel comfortable.

And then as I noted, we have the listening sessions, and this is the opportunity for spoken comment. We do ask that measure developers be on the line to answer any specific questions. I did mention the advisory group meetings. Now, this is more of a listen-only opportunity where you as the developer and steward do get to listen in on some of the group discourse, but there is no opportunity for interaction with the advisory group. It's really just more of a listen and learn.

And then we do have our recommendation group. Here we also, similar to the listening sessions, ask you to be on to answer questions and provide clarification. We want to make sure that all of the committees have an accurate understanding of the measure prior to their vote. And with that, I'll turn it over to you, Jake.

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WEBB: Thank you, Kate. So before we get to the Q&A, I just wanted to talk about some support and resources that you might find helpful as you're submitting your measures this year.

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CMS MERIT Support

Quick Start Guide and **2025 MERIT Data Template** are available for download on log in page

CMS MERIT Tips & Tricks Session
April 8
12:00 P.M. ET

? Contact MMSsupport@battelle.org with CMS MERIT questions

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WEBB: As I mentioned earlier in the webinar, we do have a Word version of the CMS MERIT tool called the "MERIT Data Template," which is available to download, as well as the CMS MERIT QuickStart Guide for submitters that are found on the CMS MERIT login page. We will share that link with you in the chat. Additionally, as I mentioned earlier, we are going to be having a CMS MERIT Tips & Tricks session on Tuesday, April 8th at 12:00 pm ET where we will be doing a live demo walkthrough of the CMS MERIT tool. This is a great webinar if this is maybe your first time submitting with CMS MERIT, or maybe you just need a refresher. It also would be beneficial if this is your first time submitting a composite or survey measure and kind of seeing how that new process will look.

 If you can't attend, do not worry. We will be recording and posting it to the pre-rulemaking resources tab on the MMS Hub shortly after the events, and the link to register should be in the chat as well. Finally, if at

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any time during the process you have any questions, please reach out to us at MMSSupport@battelle.org. So now I really quickly just want to transition to a brief screensharing tour, just to go over a couple of the resources that we've talked about, and then we'll end with the Q&A.

DEMO
[SLIDE 44]

Pre-Rulemaking Resources

Tour of Pre-Rulemaking Webpage
Pre-Rulemaking | The Measures Management System (cms.gov)
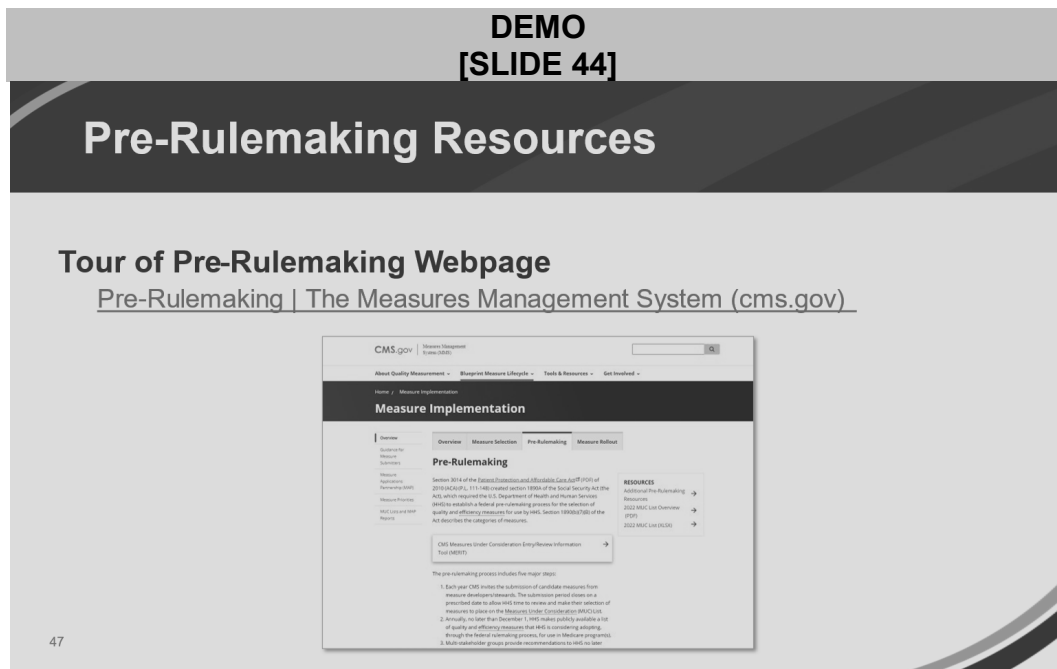
WEBB: So the first website I just wanted to kind of touch on is the actual CMS MERIT tool itself. So this is the homepage, and you actually find a lot of resources on this first page. So, as I mentioned, down here you can see the MERIT Data Template and the QuickStart Guide. So these are found here. You can also find them on the pre-rulemaking resources, but they're both able to be downloaded — one's a PDF, one's a Word document. You can also find a link to the actual pre-rulemaking webpage here as well. And then there's also a brief animated video that we created that kind of talks about CMS MERIT's purpose, the features, and the role in pre-rulemaking. So it's a very condensed version of today's

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presentation. If you haven't seen it already, I recommend watching it just to kind of learn a little bit more and then maybe also sharing with colleagues as well.

If you don't already have a CMS MERIT account, I strongly recommend doing that sooner than later. It does take about 24 hours for us to create that account for you. So it's better just to do it now so you don't forget and have to do it, you know, closer to the actual registration time. So if you need to request an account, there's a button down here below the "forgot your password" or "request an account."

On here it's just going to ask for basic personal information like your first and last name, company, email and phone number. It's then also going to ask you what you would like access to. I do want to note that if you have access to CMIT, that does not automatically mean that you have access to MERIT. They are two separate tools, and you have to request them separately. However, if maybe you don't have both, you are able to sign up for both of those at the same time. So just to save you a little bit of time if you were looking at maybe getting a CMIT account, you could do that at the same time.

Once you have this all filled out, you'll go ahead and click that "submit request." Once you submit it, you should get a notification letting you know that your submission was submitted. And then once your account has been created, in that 24-hour period you'll get a notification that your account has been approved. And then the next step is to set up your two-factor authentication (2FA).

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The next one I just wanted to talk about is the MMS Hub. The MMS Hub, we actually have two different locations for pre-rulemaking resources. From the homepage I do actually just want to point out a feature, "news and events." We have announcements for pre-rulemaking that we put on the Hub, so you can actually see it here. This one is the announcement of opening MERIT. We also will be putting announcements of when MERIT is closing, reminders, and the Tips & Tricks webinar is on here as well. So this is just something really good to have in your back pocket as well for updated announcements and things like that. Not even just pre-rulemaking, but just MMS-related in general.

We also have a quick link here for the pre-rulemaking resources. If you're looking for a full process, if you come up to "*Blueprint* measure lifecycle," and then down to "measure implementation" there's a "pre-rulemaking" section. And really quickly the first tab is just an overview, and so it's high-level information. It's some things that we've talked about today, and so the process, the high-level timeline. There's a section on guidance for measure submitters, and so this is where you'll find information like when is the MUC List going to close? So you can see here we have the 8:00 pm ET on May 1st deadline. We also have the link to MERIT. We also have the data template and the QuickStart Guide here as well, and so there are multiple locations to find that information.

"Measure priorities" is a tab that we have that just talks about certain things like the Meaningful Measures Initiative. We have the *Needs & Priorities Report* that Mel talked about here, and just a little bit of other information such as the CMS inventory tool and the Quality Measure Index (QMI) as well.

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Here is the data repository that we were talking about of all the past MUC Lists. So you can see here from 2011 all the way to 2024 that we have the MUC Lists. We also have a MUC List recommendation report section. Under the MUC List and recommendation reports, we also have a subsection. Right now it's titled "2024 MUC List Supporting Materials." This is when I talked about the 508 documents. When measures are approved for the MUC List, we will take those attachments and make a ZIP file and upload them here for those committee reviews.

So you can see here for 2024 that we have them categorized. So this one is post-acute care (PAC)/long-term care (LTC). These are all the measures that fall in that category that were accepted or approved for 2024 in a ZIP downloaded file that are all 508-compliant attachments. This will update annually, and so this will be updated for 2025 and so on.

The other location that we have resources is under "tools and resources" and the "pre-rulemaking resources" tab. So some of this will be very similar. So again, we have the MERIT link. We also have the data template and the QuickStart Guide. This is where we also house a frequently asked questions (FAQ) document that we update annually. So that might be something if you haven't seen it already, it might be something to take a look at.

We also have the *Needs & Priorities Report* here as well. And then this is also where we house the information from the webinars that we do. So today's recording, the slides that will be uploaded shortly after today's call, and then a Q&A document of any questions and answers (Q&As) that we have from today's call. It will be uploaded on this page. Similarly, when we have the Tips & Tricks webinar, those will be shown here as well.

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The last thing I just wanted to point out is on this page there's also a "MIPS resources" section. This is where you'll find the 2025 MIPS peer-reviewed journal articles. Currently, those are still being finalized, so right now we just have a section saying "documents coming soon." We are planning on once those documents are made available that we will send out a communication to let anybody know that those are ready, because that is a required document for anybody submitting to MIPS. So once that documentation is ready, we'll let everybody know to come back before submitting.

And with that, I will go ahead and pass it back over. I think we can go ahead and start the Q&A.
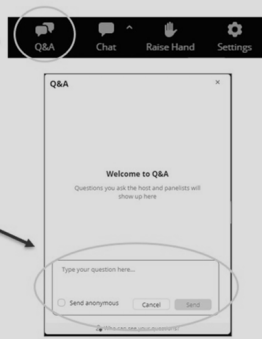
Q&A
[SLIDE 45]

Questions

Open the Zoom Q&A function →

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

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Q: "If a measure is submitted without complete testing results,

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> *what is the process for providing updates to the MUC submission with measure testing results?"*

WEBB: So measure submitters should submit their most up-to-date and complete measure testing results prior to the closing of CMS MERIT at that 8:00 pm ET deadline on Thursday, May 1st. There is no option for submitters to update measure testing information in MERIT once the submission period has closed; however, there will be a section around the fall where updated testing data will be requested by CMS.

> *Q: "Could you clarify how Battelle addresses developer feedback on the PAs?"*

BUCHANAN: Yes, so what I want to emphasize is that we aren't trying to catch anyone out. We want to collaborate with developers so that the most accurate review of the measure is presented. To that end, we will make changes that align with the spirit of the PA and are backed by evidence. If it's a revision that doesn't have evidence — or goes against something that maybe the MUC List or CMS guidance had — we will communicate that back. Also, if people would like to have a call to discuss some of their feedback, we are happy to do that. We just want to work together and make sure that we're presenting the information in a way that is true to the spirit of the measure and that the developer and steward feel comfortable with.

> *Q: "Is the information that I submit on CMS MERIT accessible to anyone to see it?"*

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WEBB: So measure information that you input into CMS MERIT is viewable to anyone with a CMS MERIT account. CMS MERIT accounts are granted to any parties that requests one. Again, should your measure be accepted onto the 2025 MUC List, all of those attachments that are submitted to CMS MERIT will also be made available on the MMS Hub website to assess, or to assist with the PRMR review as well.

Q: "What are the current priority topics for measures in CMS programs?"

GROSS: So one thing that I do want to point out is that again, we have that *Needs & Priorities Report.* The programs have identified those high-need areas for their specific program, but with that said, CMS has an interest in the following topics, which are physical fitness, nutrition, and chronic disease. Thank you.

Q: "So on Slide 26, what do you mean by 'systematic measure assessment?'"

MCNINCH: So CMS always wants to fully utilize every piece of submitted data to evaluate the measures as objectively as possible. So by doing that and so by evaluating them in a systematic and a standardized way, they're able to make robust decisions related to development, selection, continued use, and the removal of measures. They're really able to accomplish this goal by looking closely at the submitted data that doesn't require additional review and assessment alongside the more qualitative approaches of the consensus-based entity (CBE) process, for example. So refinements to selection options to be explicit and mutually exclusive is one of the ways that we aid this process. Thank you.

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WEBB: So anybody can submit measures for consideration, and on that CMS pre-rulemaking guidance for measure submitters webpage that we just visited on the MMS Hub, it does discuss the requirements and the steps for measure submission. So if that's something that you're interested in, please look at that website. Thank you.

Q: Will there be education on eCQM development?

MODERATOR: We just want to highlight that we have previously hosted presentations on digital quality measurement and eCQMs that are available on the MMS Hub website on the "educational resources" page. Just a reminder, this webinar and lots of other helpful measure development resources are available on the MMS Hub. We always welcome ideas for future webinars or resources. So if there's anything in particular that you're interested in, please be sure to email us at MMSSupport@battelle.org with your ideas.

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[SLIDE 46]

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MODERATOR: So with that, thank you so much for attending today's information session, and the recording will be made available on the MMS Hub. Thank you very much.

WEBINAR CONCLUDES

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