PUBLIC WEBINAR

2024 Pre-Rulemaking Preview

Melissa Gross, CMS

Meridith Eastman, Battelle

HOLST: Good afternoon and welcome to our December Information Session, the 2024 Pre-Rulemaking Preview. My name is Haley von Holst, the Information Session Lead for the CMS Measures Management System (MMS) contract supported by Battelle. We have Mel Gross and Meridith Eastman here today. They'll be our presenters this afternoon. If you would like to download today's slides, they are available on the CMS MMS Hub. We will also post a recording of today's session on the MMS Hub in a few weeks.

As part of the Measures Management System's outreach task, CMS produces these Information Sessions throughout the year to educate about quality measurement topics and engage those interested in measure development and maintenance. So in short, we host these sessions for you all. We highly encourage you to submit questions throughout today's presentation, and we'll try to address as many as we can at the end. All right, I'm going to turn it over to Mel to get us started today.

[SLIDE 2]

Agenda

The purpose of today's webinar is to discuss Pre-Rulemaking and prepare measure submitters for the 2024 Pre-Rulemaking Cycle.
Topics we'll cover include:

- Orientation to the Pre-Rulemaking Process
- Pre-Rulemaking Timeline
- Updates to the Centers for Medicare & Medicaid Services (CMS) Measure Entry/Review Information Tool (MERIT)
- Upcoming Pre-Rulemaking Education and Outreach Activities
- Pre-Rulemaking Resources

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GROSS: Thank you. As Haley had mentioned, my name is Melissa Gross, and I am the task lead for pre-rulemaking for CMS. I work closely with Battelle on the pre-rulemaking work. So today we are excited to present to you and discuss the pre-rulemaking process and the timeline and just give a general synopsis of what happens and give a little bit of an orientation. We will talk about the pre-rulemaking process. We'll talk about the timeline. We will show and discuss updates about our tool, MERIT, which is CMS' Measure Entry/Review Information Tool. So that's where all of the measures are submitted.

And then we'll talk about other pre-rulemaking, education and outreach activities, and we'll share some other pre-rulemaking resources that will help along in the process down the line.

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Pre-Rulemaking Orientation

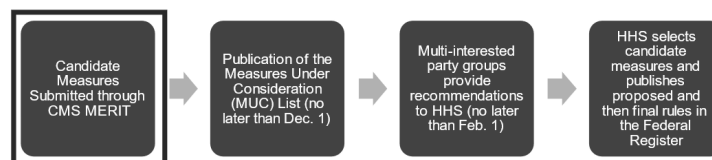3   12/12/2023

GROSS: Okay. So right now we're going to focus on just the general highlights of pre-rulemaking.

[SLIDE 4]

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**.

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 candidate measures and publishes proposed and then final rules in the Federal Register

Today's focus

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GROSS: So to start, it's important to understand that CMS and the Department of Health and Human Services (HHS) is statutorily required to have a pre-rulemaking process for the selection of quality and efficiency measures, and for the use of those measures in HHS.

So what we are talking about today is the process of submitting those measures through CMS MERIT, but then you can see along this bottom row of blocks that there are other stages. Many of you, if you are already involved in the process, know that on December 1st annually we publish the measures under consideration (MUC) which is not even a week behind us. We just published the 2023 MUC List. We then have a multi-interested party group provide recommendations to HHS no later than February 1st. And then HHS selects those candidate measures and publishes and propose those proposed and the final rules eventually in the Federal Register.

[SLIDE 5]

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 Rating
Prospective Payment System-Exempt
Cancer Hospital Quality Reporting
Rural Emergency Hospital Quality Reporting
Skilled Nursing Facility Quality Reporting
Skilled Nursing Facility Value-Based Purchasing

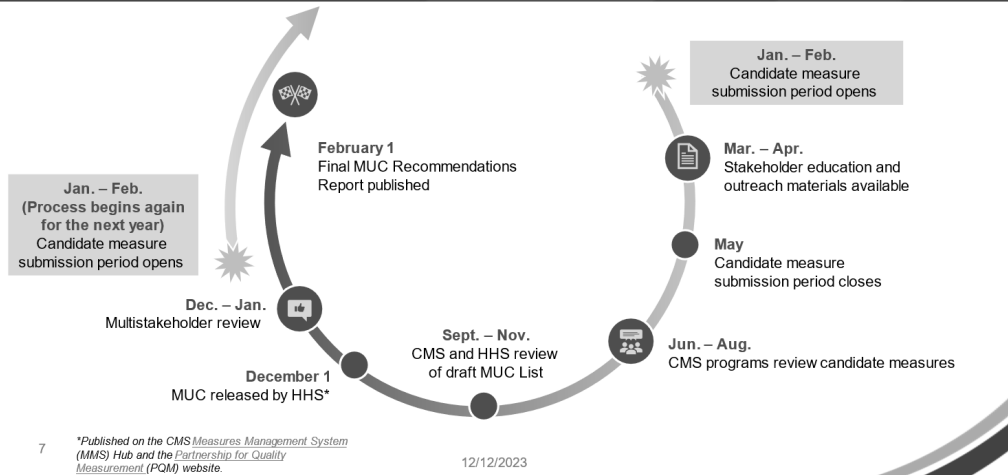5   12/12/2023

GROSS: So if you're at all curious, the programs that participate in our pre-rulemaking process are listed here. I'm not going to read them all, but these are all of the programs that annually participate in this process. So you'll probably be familiar with a lot of the programs, or some of them. I'm going to now pass it over to Meridith Eastman from Battelle to discuss further details and highlights of pre-rulemaking.

[SLIDE 6]

Pre-Rulemaking Timeline

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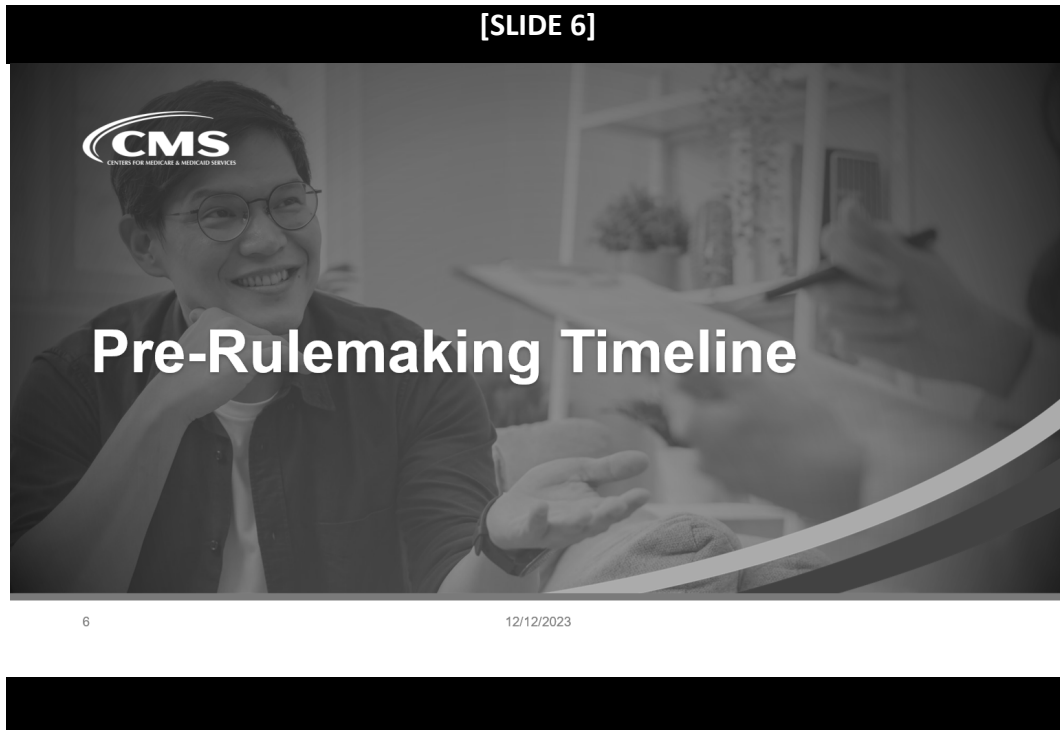
EASTMAN: Thanks, Mel. So Mel just gave a high-level overview of the process with those blocks that we saw at the bottom of that one slide.

Cyclical Pre-Rulemaking Timeline

Jan. – Feb.
Candidate measure
submission period opens

Mar. – Apr.
Stakeholder education and
outreach materials available

February 1
Final MUC Recommendations
Report published

May
Candidate measure
submission period closes

Jan. – Feb.
(Process begins again for the next year)
Candidate measure
submission period opens

Dec. – Jan.
Multistakeholder review

Sept. – Nov.
CMS and HHS review
of draft MUC List

Jun. – Aug.
CMS programs review candidate measures

December 1
MUC released by HHS*

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

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EASTMAN: Here we can see a little bit more detailed view of the cyclical pre-rulemaking timeline. So to complete all activities associated with pre-rulemaking it takes actually 13 months. So it's over a year long. You can see that there's sort of a little overhang there, as Mel mentioned, because we've just wrapped up the 2023 pre-rulemaking cycle. Now at the same time we're also preparing to launch the 2024 pre-rulemaking cycle at the end of January. So you see that yellow box on the right. That is showing when CMS MERIT, our web tool for submitting measures, opens for candidate measure submissions.

And then in March and April we hold a couple of informational webinars and issue some additional materials for things like the *Program-Specific Needs & Priorities Report*. We make that information available, and we'll talk about kind of that stretch of time a little bit more detailed in a few minutes. The measure submission period closes in May, and then the candidate measures undergo
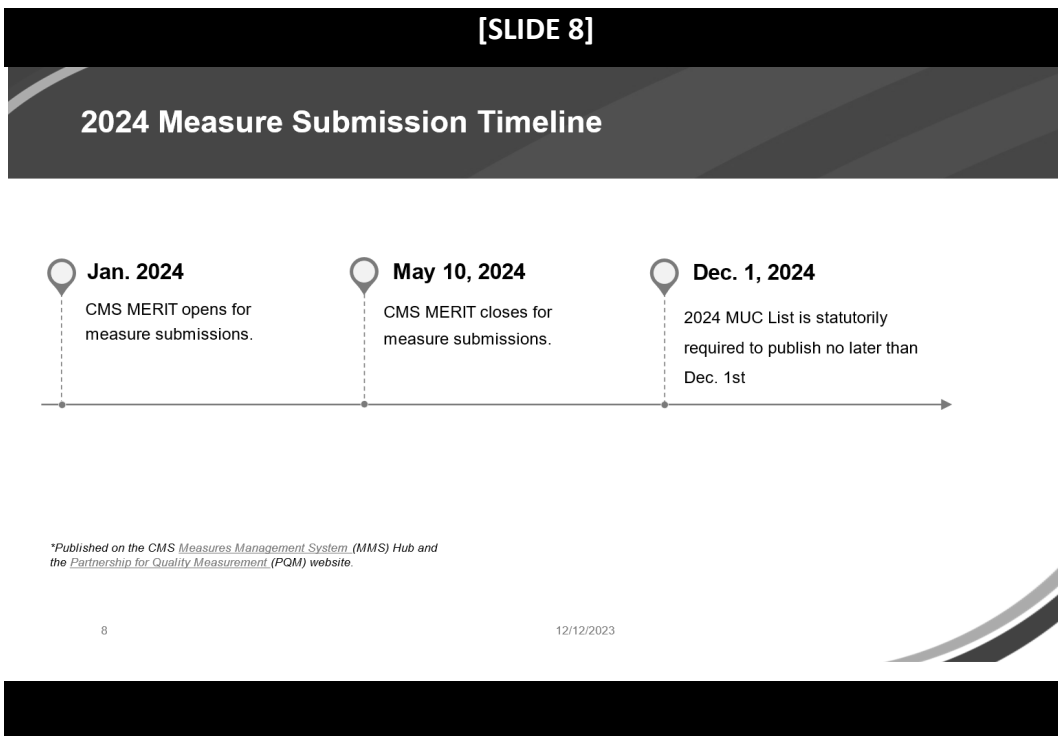
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several rounds of review at CMS and we draft the MUC List. The MUC List then undergoes CMS and HHS review in the fall. And then the list is released by HHS and is published to the MMS Hub and the Partnership for Quality Measurement (PQM) website. Again, that happens no later than December 1st each year.

The measures on that list undergo multi-stakeholder review in December and January. The final measures under consideration (MUC) recommendations report is published by the Partnership for Quality Measurement (PQM) by February 1st. So that horseshoe cycle shape is a high-level overview of the timeline that happens every single year, but you may be interested in what the specifics are for next year, for 2024.

[SLIDE 8]

2024 Measure Submission Timeline

Jan. 2024
CMS MERIT opens for measure submissions.

May 10, 2024
CMS MERIT closes for measure submissions.

Dec. 1, 2024
2024 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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EASTMAN: So we expect CMS MERIT to open for new measure submissions at the end of January 2024, and the deadline for submitting measures next year will be May 10, 2024. And then as per the statutory requirement, the MUC List will

be published by December 1, 2024. So those are our kind of major signposts for this year on this slide. Again the MUC List will get published to two places — on the MMS Hub and also the Partnership for Quality Measurement (PQM) website.
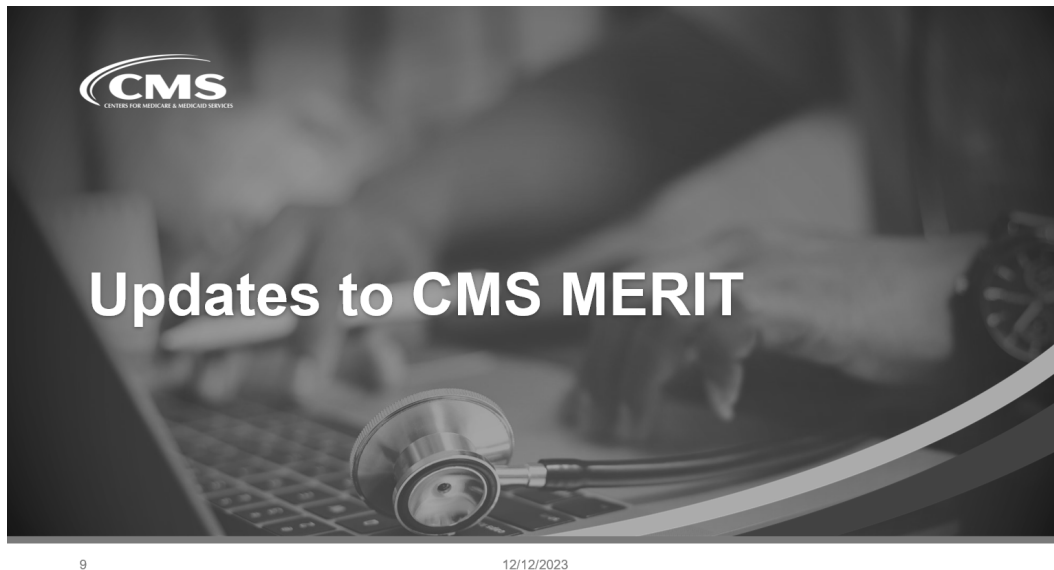
EASTMAN: So every year we actually evaluate the questions in CMS MERIT and the functionality of the tool to make sure that everything is still in alignment with CMS and other stakeholder needs.

POLL

EASTMAN: So before we talk about the specific updates that are coming down the pike for next year, we're actually going to put up a quick poll to see how familiar you all are with CMS MERIT. Please take a minute and just answer this single question that we have up there. We'll just take a pause and allow you to

respond. Okay, thanks to everyone who responded. Jake, would you be able to fill us in on how folks answered this question?

WEBB: Yes, so as of right now it looks like about 63% of everybody who is in attendance has submitted. As of right now, it looks like about 16% have used MERIT before; 76% have not, and 8% have not but are planning to in 2024.

EASTMAN: Super, thank you. That's Jake Webb, our Zoom manager extraordinaire. Thank you, Jake, and thank you all for answering that question. It sounds like we have a mix of folks who are pretty familiar with MERIT, and those of you who may be new to the tool in this next cycle. We're happy to welcome you into the fold for 2024.

[SLIDE 10]

Updates to CMS MERIT

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

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EASTMAN: So CMS MERIT, as we've said, is the tool that measure developers use to submit measures for consideration by CMS. Those of you who have used MERIT before will be pleased to hear that there are actually fewer required fields to complete in 2024. In fact, there are about 30 fewer fields in total, and so we hope that that will be good news to many of you.
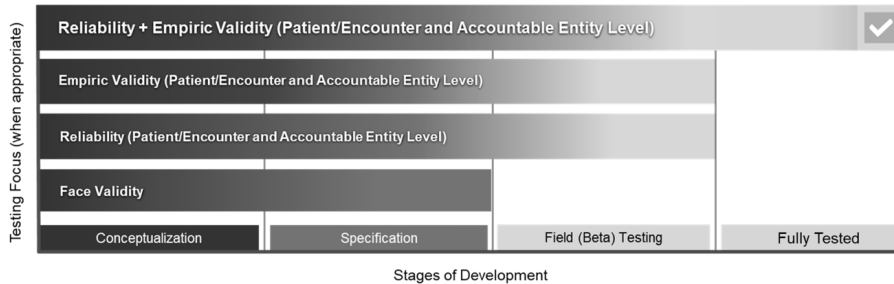
In addition to that overall reduction in the number of fields, there are a few other updates for implementing that we wanted to share. First is a rather straightforward one. We've updated background questions so that they refer to the new Pre-Rulemaking Measure Review or the "PRMR" process [pronounced "primer"] which was formerly known as the MAP. So you'll now see reference to PRMR in the tool as you're answering questions.

There is a new required question introduced in 2024, specifically for measures that use patient surveys or tools. The new question asks whether these instruments have been translated and validated in Spanish, and so you'll see that question, and it's a required question for measures that use patient surveys and tools.

Lastly, there's a revised stage of development question that asks submitters to indicate which stages of development have been completed for the measure. So previously the question just asked what stage the measure was in, but now we're asking you to indicate the completed stages of development.

Stage of Development

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

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	Field (Beta) Testing	Fully Tested	

Stages of Development

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EASTMAN: So in this graphic you'll see the stages of development at the bottom of the slide here. We wanted to take just this opportunity to remind folks that CMS will evaluate measures at all stages of development but prefers measures that have been fully conceptualized, specified and tested. What "fully tested" means is conveyed in this graphic on this slide. So it's expected that fully tested measures will have undergone reliability and empiric validity testing at both the patient encounter level, and so what was formerly known as "data element" level, and at the "accountable entity" level when appropriate. So you can kind of see how that top line leads to the checkmark above "fully tested."

CMS MERIT Data Template

The 2024 CMS MERIT Data Template (i.e., the Word version of MERIT questions) will be available for download when MERIT launches for the 2024 cycle at the end of January.

- The CMS MERIT Data Template will be accessible from the CMS MERIT landing page, with no login required.

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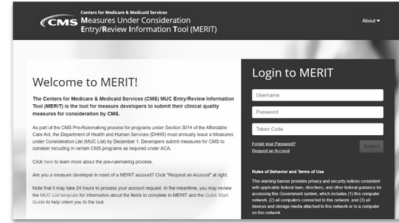
EASTMAN: So each year as we make updates to CMS MERIT the web tool, we also prepare a Word version of the questions in MERIT, which we call the "CMS MERIT Data Template." This is a helpful document that you can use to draft your responses in advance, and you can share that document with colleagues for input depending on your own process. So we will be making this document available for download for the 2024 cycle at the end of January when MERIT opens for measure submissions.

We make this template available right from the CMS MERIT landing page, and so you can actually access it without even needing to log in. We have a little picture of the CMS MERIT landing page there on the right. Just to note, if you do plan to submit a measure and you don't have a CMS MERIT account, you will need to get one. You can request an account from that CMS MERIT landing page as well.

Learning More About Pre-Rulemaking

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EASTMAN: So today's webinar is intended to be a preview of what to expect for the upcoming pre-rulemaking cycle, and this will not be your only opportunity to learn about pre-rulemaking. We have some opportunities and resources that we wanted to call your attention to that will be available to support you through the 2024 pre-rulemaking cycle and the measure submission process. So first I'll talk about our education and outreach activities.

Pre-Rulemaking Education and Outreach Activities

- Each year, CMS hosts a public pre-rulemaking webinar to review pre-rulemaking policies and processes.
  - The 2024 pre-rulemaking webinar will be held **March 28.**
- Each year, CMS hosts a training session on CMS MERIT.
  - The 2024 CMS MERIT Tips & Tricks session will be held **April 9.**

- Slides and recordings for both events will be posted to the Pre-Rulemaking Resources page on the CMS Measures Management System (MMS) Hub.

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EASTMAN: So each year CMS hosts a pre-rulemaking webinar, a public webinar, to review pre-rulemaking policies and processes. This is often referred to as the "Pre-Rulemaking Kickoff Webinar," though it happens a couple of months after we launch MERIT. This year the 2024 pre-rulemaking webinar will be held on March 28th. Subsequent to that webinar we also host a training session specifically on how to use CMS MERIT, the web-based tool. We call that the "CMS MERIT Tips & Tricks" session. It's really a training and demonstration on how to submit a measure in the system, and in 2024 it will be held on April 9th.

Generally these webinars take place in early to mid-afternoon Eastern time. Details depending on speaker availability. But if these dates don't work for you, we do post the slides and webinar recordings for both of these events to the pre-rulemaking resources page on the CMS MMS Hub.

Pre-Rulemaking Resources

- Visit the MMS Hub Pre-Rulemaking webpage to learn about pre-rulemaking processes, priorities, and view past MUC Lists
- Visit the MMS Hub Pre-Rulemaking Resources page to access:
    - Previous pre-rulemaking event recordings
    - MERIT Data Template*
    - MERIT QuickStart Guide*
    - Pre-Rulemaking Frequently Asked Questions*
    - Fact sheets and templates for the Merit -based Incentive Payment System (MIPS) Annual Call for Measures*
    - CMS Program-Specific Needs and Priorities Report**

*to be updated in January
**to be updated in March

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EASTMAN: And that is actually a great transition to talk a little more about the pre-rulemaking resources that are out there to support you through your measure submission. So there are two places on the Measures Management System (MMS) Hub that I recommend checking out to learn about pre-rulemaking and to view pre-rulemaking related documents. So the first is the pre-rulemaking webpage, and the second is the pre-rulemaking resources page.

So the webpage is a great overview of pre-rulemaking processes, priorities, and it's also where you will find past years' MUC Lists. The pre-rulemaking resources page is going to be your go-to for pre-rulemaking documents to help you with measure submission. So we post that resources page, that's where we post the MERIT Data Template, the MERIT QuickStart Guide, and there's an FAQ. We also post there the fact sheets and templates that are specific for measures being submitted to the Merit-based Incentive Payment System or MIPS.

We also post annual updates to the *CMS Program-Specific Needs & Priorities Report* there as well. We're now in the process of updating all of those documents over the next few months, and I'm actually going to take a minute and do a screen share to show you how to find all of these resources.

DEMO

EASTMAN: So you should be seeing the landing page, the homepage for the CMS Measures Management System (MMS) Hub. I'll just point out that here we have the announcement that we just published, the 2023 measures under consideration (MUC) List. But to get to the pre-rulemaking webpage, I'm going to click on the "Blueprint measure lifecycle" tab up on top. And then go to "pre-rulemaking" and then go to "overview." This is the overview page where again you can find an overview of the pre-rulemaking process. We have the statute that Mel alluded to earlier up here. The general annual timeline for pre-rulemaking is listed here as well, but you can also navigate to other pages, other sections within the page using this nav bar on the left.

So here we have guidance for measure submitters and links to some of those documents that are all consolidated in one place on the resources page that I'll share in a moment. We have a page that describes what pre-rulemaking measure priorities are and how they're determined. And then on this page, the MUC List and recommendation reports page, is where you'll find not only the current MUC List here — the 2023 MUC List — but also all of the MUC Lists from prior years. And then below that, these are the MUC List recommendation reports that get published by February 1st of each year.

Again, we encourage you to check out these resources that are available. That is the pre-rulemaking webpage, but we also have a pre-rulemaking resources page. To get there I click on "tools and resources" and then "pre-rulemaking resources." As you can see here we have a lot of stuff. This is a consolidated list of all of the hyperlinks from the pre-rulemaking webpage, a lot of the documents I've already talked about. So we have a link to MERIT. We have the MERIT Data Template, the QuickStart Guide, the FAQs, *Needs & Priorities*, and here are last year's webinars. So if you wanted to see what happened at last year's Pre-Rulemaking Kickoff Webinar, you can look at those slides and those recordings.

And then down below we have the resources that are specific to measures that are being submitted to the Merit-based Incentive Payment System or MIPS. For example, there's the peer-reviewed journal article template that is here and some other fact sheets and examples.

So now I am going to just mention that you will see a lot of changes to these pages over the next few months as we get ready to kick off the next cycle, but I just wanted to make sure that you all knew where to find the support resources as we get ready to embark in 2024.
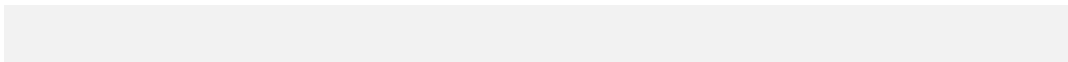
Pre-Rulemaking Announcements

- Pre-Rulemaking announcements will be posted to the MMS Hub and sent to the MMS Pre-Rulemaking email list.
  - Email MMSsupport@battelle.org and ask to be added to the MMS Pre-Rulemaking email list to receive announcements in your inbox.

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EASTMAN: So before we open it up for questions, I did want to mention that we do distribute announcements specific to pre-rulemaking during the measure submission cycle. Those announcements will be posted to the MMS Hub about where we saw that announcement about the 2023 MUC List publication. And then we also send those announcements out to the MMS pre-rulemaking email list. So if you want to be added to the email list and get those announcements in your inbox, we ask you to please send an email to MMSSupport@battelle.org. Just ask to added to the MMS pre-rulemaking email list.

So I think that's all we wanted to cover for today. We just wanted to really give you an early heads up about what to expect in this next cycle, and we are looking forward to supporting you through the measure submission period in 2024. So with that I think I will turn it over to Haley to see if we've received any questions.

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Q: *"What is the deadline for submitting measures in CMS MERIT?"*

EASTMAN: The deadline is May 10, 2024 at 8:00 pm ET, and that is a Friday. We set that deadline to allow sufficient time for CMS review of the measure information, for drafting of the MUC List, and also for getting the MUC List through the federal clearance review process so that we can meet that December 1st statutory deadline, but again the deadline for measure submissions in 2024 will be May 10th at eight o'clock.

Q: *"How will I know when CMS MERIT is open for measure submission?"*

EASTMAN: So we're aiming to have CMS MERIT go live on the last business day of January. So when it is available and when it's officially open for the 2024 cycle, we'll send an announcement out to that pre-rulemaking email list that I mentioned on the very last slide. We'll also post an announcement on the MMS Hub, and so you will learn when it's officially open by that Hub posting, or through that email. Again, we are aiming to open MERIT on the 31st of January which is the last business day of January.

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

EASTMAN: So the measure information that you input into CMS MERIT is viewable to anyone else who has a CMS MERIT account. So you would need an account, but you will be able to see any information that's input there. CMS MERIT accounts are granted to any party that requests one, and so essentially the short answer is *yes*. The information you submit into MERIT is publicly accessible.

> Q: "How long does it take to receive a MERIT account
> after you submit a request?"

EASTMAN: I believe we anticipate a 24 to 48-hour period to set up that account. So if you haven't heard, do contact us at MMSSupport@battelle.org. Do also check your spam filters, because sometimes those emails end up there, but it should just take 24 to 48 hours to get that account once you request it.

> Q: "Can CMS describe how programs determine
> their measure needs and priority?"

GROSS: It really does vary by program, but ultimately the program-specific statutes can indicate where those priorities may lie, as well as there might be other priorities that are agencywide that are promoted and that the programs try to fill a gap if necessary. So those can be things like health equity or maternal health, but a good way to see what a program's profile looks like is to look at the *Needs & Priorities* document. It gives a beautiful layout of the program, the description of the program and its purpose, and the amount of measures that they have.

And then it can highlight where there might be measures or areas, domains that need to be fulfilled. Programs also use the Meaningful Measures 2.0 Initiative, as well as the Cascade of Meaningful Measures Framework or tool to identify priorities and gaps in their measure portfolios. So then the *Needs & Priorities* document can be a very helpful resource for measure developers and anyone interested in quality measures.

> *Q: "Where is the pre-rulemaking calendar available?*
> *How many years in advance are calendars published?"*

HOLST: Mel has responded to that one, and so just noting that the calendar is relatively stable. You can use the slides from today's presentation as a reference to the timeline, or refer to that MMS Hub for the pre-rulemaking dates and resources.

> *Q: "Can you talk a little bit about the public comment*
> *sessions that are coming up?*
> *What kinds of comments are traditionally heard in these meetings?"*

EASTMAN: So I think for that question we'll need to refer you to the Partnership for Quality Measurement (PQM), which is over at the website. We'll pop the link in the chat to the Partnership for Quality Measurement (PQM)website. They're actually handling the multi-stakeholder review, the PRMR review for this year's MUC List.

HOLST: All right, wonderful. Well, I think that is all we have today. Again, if you asked a question and we didn't talk about it today, we'll do our best to follow up. It might take some more discussion on our end, but we really appreciate the discussion and the engagement. So yes, thank you for attending today's session.

[SLIDE 18]

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HOLST: And then just a reminder to please visit the MMS Hub for upcoming events and opportunities to get involved in the pre-rulemaking process. Yes, thank you for attending.

WEBINAR CONCLUDES