QCDR Measure Development Webinar

February 13, 2025

>> Ketchum: Hello, everyone. Thank you for joining today's Qualified Clinical Data Registry, or QCDR Measure Development, webinar. This presentation will be followed by a Q&A session where attendees will have an opportunity to ask questions via the phone and Q&A box and CMS subject matter experts will address as many questions as time allows. You're welcome to submit your questions during the presentation or wait to submit your questions until the Q&A portion of the call. As a note, the slide deck and recording from today's session will be posted on the QPP Webinar Library in the coming weeks. I will now turn it over to Dr. Green from CMS to start the presentation.

>> **Dr. Daniel Green, CMS**: Thanks, Hallie. Next slide, please. So, great. I just want to welcome everyone. Thank you all for your interest in our program and for interest in submitting measures potentially to CMS for consideration in the Quality Payment Program. My name is Dan Green. I'm a medical officer in the Division of Clinical Quality in the Center for Clinical Standards and Quality here at CMS.

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And this is our standard disclaimer that we have in all of our presentations.

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So today we're going to talk about QCDR measure overview and requirements. We're going to talk about some of the basics and also measure development. QCDR measure review and tips for successful submission. So we'll go over ways that will help you be successful when you submit measures to us for consideration. We'll talk about the measure testing requirements. We'll also briefly discuss the transition to MVPs, which we believe is the future of the MIPS Quality Reporting Program. There'll be-- resources will be displayed with links as well as question and answer session. So before we actually get into the meat of the presentation. I'm

going to turn it over to Dr. Ron Kline. Dr. Kline is a pediatric oncologist and the Chief Medical Officer in the QMVIG group. So he's my boss. He's going to tell us briefly kind of some of the things that we're actually looking for in measures to give you guys a better idea of what we would consider important and obviously improve the chances that a measure concept or a measure that you submit to us would be accepted into the program. So without further ado, Dr. Kline.

>> **Dr. Ronald Kline, CMS**: Yeah, thanks, Dan. So good afternoon and good morning to everyone, depending on what time zone you're in. I'm just going to just chat for just a couple of minutes to give you some sense of, you know, what we're looking for in measures because we really value our relationship with QCDRs and QCDR Measure Developers and we want our relationship to be productive, you know, successful and cooperative. What we don't want to have happen is to have a QCDR, QCDR Measure Developer spend a large amount of time, money, effort on a measure only to have CMS rejected. It makes for, you know, unhappiness on your side. It makes for unhappiness on our side. So we want to work really hard to try to avoid that as measures are presented to us. So there are a couple of criteria that we have when we look at a measure and we'll pass those along. I think those that will improve the chances of your measure being accepted. So first, we want to meaningfully raise the bar in quality. And by that, I mean, we're here at CMS because we want to improve the quality of care for the American people. And we believe the QCDR Measure Developers, you have the same intent. And so the measures we see have to really be a little bit aspirational. They have to ask people to do a little bit better than what they're doing. It can't just simply be a standard of care measure. And a lot of times we look at measures and we say, well, “isn't that sort of a normal part of what you should be doing every single day with your patient?” And the answer oftentimes is “yes”. And in the past, we've often accepted those measures, but I think moving forward, we're going to be a little bit more strict in terms of really trying to raise the bar. So, please when you work on a measure, you know, tell us that there's a gap, that this is going to improve the quality of care as opposed to, yeah, this is what the doctor's supposed to do every day when they see their patient.

I think that the other component here is we want to minimize the clinician burden. And I want to say digital measures are what we look for but I know there's so many different definitions of

digital. So I'll just clarify that a bit. We don't want chart-abstracted measures. We don't want measures where people have to go through charts and do this. We want things that are electronically sourced and whether you call them an eCQM or a Digital Measure or whatever you call them, we really want to make for minimum clinician burdens. So that would be the second component. I think we have a lot of topped-out measures in our program. And oftentimes we look at those and sometimes we remove them. And sometimes we don't remove them because there are so few measures for that specialty. But again, moving forward, you know, I think we're going to look harder at topped-out measures. And so what we'd love to see is to have you as developers develop aspirational measures that aren't topped out so that we can remove some of the ones that are topped out. Also, when you think about what you're doing, a lot of times we have, I don't know if you want to call it, the minimally acceptable quality measure in the sense that it slices and dices, you know, a disease category into three or four different quality measures, you know, one for this type of dermatological disease, one for that type of dermatological disease, or this type of neurological disease, or that type and neurological disease. And what we really would like you to do is to combine those measures as appropriate for a specialty. So if it's for a neurologist, for instance, it might incorporate several diseases that a neurologist might see, not three separate measures for each of three separate diseases. And the last thing I'll say, and I say this as a pediatric specialist, is we would like to see measures incorporate the pediatric age group as appropriate. So it's not always appropriate, you know, for a pediatric age group to be involved in a quality measure, but oftentimes it is. And sometimes when we've had our meetings with folks and we say, well, why is it 18 and above? Doesn't this also affect kids? And the answer is, yeah, but we just said 18 and above because that's what we always do. So please think a little bit harder about your measures and whether it's appropriate to include a pediatric age group in that category. And with that, I will end and I wish you guys a pleasant meeting. And on to the next person.

>> **Stacy Sams, PIMMS**: Thank you, Dr. Kline. This is Stacy with the PIMMS team. Thank you again for joining us today. And we're going to begin just looking over a high-level timeline of processes that occurred during the self-nomination period and things that QCDRs will encounter through the process. And hopefully, this information will help you during your measure development or as you self-nominate your QCDR measures.

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So this first slide shows just a very high-level timeline of the processes that QCDRs can expect through the self-nomination period. The annual Self-Nomination period usually opens on July 1 and ends on September 1. These days may differ from a day or two depending on if they would fall during the weekend. And just to help QCDRs submitting their Self-Nomination. CMS does publish several very helpful resources to the QPP Resource Library prior to the opening of the Self-Nomination. And these will help spell out the requirements to be a QCDR and also just have information to help you Self-Nominate your QCDR measures. And you can look for this on the QPP Resource Library will also announce when this gets posted. So beginning on July 1, QCDRs will be able to start Self-Nominating themselves to be a CMS-approved QCDR, and that this time they'll also submit their QCDR measures that they want CMS to consider for the upcoming performance period and all of this will be completed through your QPP Self-Nomination Form. And everything must be completed within the set dates of the Self-Nomination period. And once the Self-Nomination period closes, all QCDR measures that were submitted will be reviewed through multiple levels of CMS Leadership and either approved for the program or rejected. However, all rejected measures do go through a second level of review with CMS Leadership before they're finalized. From there, we'll communicate all measure decisions to each QCDR that submitted measures. Excuse me. And we do provide the option for QCDRs to request a reconsideration call for any rejected measures. And these calls just allow QCDRs to formally appeal rejected measure decisions and discuss with CMS just to be reconsidered. And following the reconsideration calls, all the measure decisions will be finalized and we'll work with each QCDR to reconcile all the specifications for approved measures. And those will then be publicly posted on the QPP Resource Library, and then QCDRs will be required to also post their specifications on their individual website and share that link with CMS.

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So the next couple of slides will touch on some requirements that you should take into consideration prior to Self-Nominating QCDR measures. First of all, we want to see-- CMS wants to see all measures beyond the measure concept phase and be fully developed. When you submit the measures, you're going to be required to provide full specifications and supporting evidence for the measure and why the measure is clinically relevant. This evidence should show proof of the gap in the performance data and show variants in clinicians' performance. It is one of the bigger things considered when CMS reviews measures. And CMS will expect there to be data to show that there's measurable room for improvement and variation.

Outcome measures are generally preferred over process-based measures. And these include the measure types of outcome, intermediate outcome, and patient-reported outcome-based performance measures, also known as PRO-PMs. The current QCDR measure testing requirements must also be met. Currently, new measures being submitted for the first performance period are required to have a minimum of face validity, and measures submitted for subsequent performance periods must be fully tested and developed. Marla will be touching a little bit-- touching on a little more testing detail later in the presentation. Additionally, CMS is not looking for measures whose concepts are already addressed, either in a current or retired MIPS quality or QCDR measure. The CMS does take past and present measure inventories into consideration when they do reviewing of QCDR measures. And that's why it's important when developing measures to complete a thorough environmental scan just to avoid duplicating measure concepts.

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So when the QCDR measure is Self-Nominated, the measure must be submitted in its entirety with fully developed specifications, and QCDRs are expected to be able to collect and implement the measure by January 1 of the performance period that it's approved for. Another reminder, just regardless of a measure's decision from a prior year, if it's currently in the program, all QCDR measures must still be resubmitted and reviewed by CMS every year.

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So, the last process that we work through after all the measure decisions are finalized is working with QCDRs to confirm their specifications for approved measures. CMS then publicly posts all the approved measures to the QPP Resource Library, and then after this posting, the QCDRs are required to post their measures on their individual websites. We will work directly with each QCDR to ensure this is completed within the 15-day requirement. We also want to remind you, QCDR measure specifications should remain posted through the performance period they're approved for, but also the submission period. We've experienced in the past just QCDRs were taking their specifications down from their website at the end of the performance period. But we ask that you keep those posted through the submission period, as well.

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Finally, when you submit a QCDR measure in the Self-Nomination Form, there is a required field where you will link your QCDR measure to either a cost measure, improvement activity, or an MVP. And if the measure doesn't happen to align with any of those, then we would ask that you would provide a rationale for an exception. CMS will consider exceptions if the rationale is provided, and all other measure requirements and considerations are met for that measure. Just one example would be if a particular specialty is not currently reflected in the cost inventory. And the purpose of this is for the creation of MVPs, and it's just helpful to correlate QCDR measures to the other performance categories. It just helps to develop more robust and cohesive MVPs for the MIPS program.

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So, we're now going to take a look at some QCDR measure basics and some guidance on measure development.

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So a few additional considerations that CMS may take into account during your measure reviews is measures should be evidence-based and they should also include a meaningful quality action. When measures focus on a change in a patient's health status, resulting from the care they received, it's more meaningful and a better indicator of quality of care than just checking a box that something was completed. Numerators should clearly detail the expected quality action, and those should be based on current evidence and clinical recommendations. We also look for QCDR measures not to be duplicative of other current or retired measures, as we previously discussed. Finally, the measure's performance data, as Dr. Kline mentioned, should address variation among clinicians and have the ability to show that a gap in care does exist, just showing that there's room for meaningful improvement, and it reduces the chances of the measure just performing very high and potentially topping out quickly. Sometimes a full year of data is not available, and so we request that you submit even partial data, anything that you have available. If performance data is not available, CMS will consider submission of current cited clinical guidelines or recommendations from reputable sources, and these should be preferably within the last five years.

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So, every year during Self-Nomination, we receive a few hundred QCDR measures that go under review, and we do like to share trends and common feedback that we give to QCDRs year over year just to hopefully more clearly show what CMS is looking for in QCDR measures when they're submitted. And the next few slides will just walk through some of the typical scenarios that we've seen we see.

This first one is probably the most common that we see year over year, measures that do not focus on a quality action or outcome. Measures that only capture the completion of an assessment or survey or checkbox as we have called it, are not usually pushing the needle. And it's not that they're not important. However, CMS does prefer that the measure takes the patient care even one step further and requires a follow-up plan or some type of intervention, and this just ensures that abnormal and unusual findings are being addressed and taken into consideration. Preferred outcome measures such as Intermediate Outcomes, Patient-Reported

Outcomes, another consideration, or measures that split comparable clinical processes into different measures, prefer to have a more comprehensive, robust measure that's more meaningful instead of having one measure that's broken down into several separate measures. An example would be taking the results of like three lab tests that together are required to manage a specific condition, but each lab is pulled into its own measure. And so we would just request those types of measures are combined. And I'm mentioning again, but measure concepts that are not currently available are preferred. And we would prefer that you collaborate with existing measure stewards just to make measure updates to current measures so it covers a broader patient population or clinical setting.

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So as previously mentioned before, measures that show a variance in performance between clinicians. This speaks to measures that focus on events that happen so infrequently that it's not meaningful or so-called never events, such as a fire in the operating room, for example, there would be less than a percentage difference from the top to the bottom performer and it just would not even not really identify variability, and hard to say that one clinician is doing any better than another clinician. We like to have measures that do not impose extra burden on clinicians to report the measure. So leveraging existing coding systems or choosing the appropriate collection type are just a couple of ways that the burden can be reduced. And to ensure that clinicians can effectively capture the correct patient population for a measure, we request that you further evaluate the need for denominator exclusions or exceptions, and doing this can help reduce the potential for unintended consequences and avoid instances when the quality action may just not apply to every patient that falls within the denominator population. And we also, as Dr. Kline mentioned, encourage the development of measures that go beyond what is considered the standard of care when the quality action is requiring what is already expected and performed consistently. And just an example of this would be a measure obtaining consent before a surgery where the consent before the surgery is just standard. And so these types of measures should be further assessed just for ways to include a robust quality action.

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So a common theme we've touched on already a few times are measures with similar concepts and we prefer those measures be combined into one measure and having one comprehensive measure will allow for better comparison among a larger group of clinicians and will reduce the burden by not having to choose from several similar measures to help reduce this occurrence. We encourage just a thorough analysis when you're developing measures to take into account the current and past MIPS quality and QCDR measure inventory to identify any similarities or differences that there may be.

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So, expanding -- excuse me -- expanding on measure concept duplication just a bit further. This has really taken into consideration when reviewing measures. And in some situations, CMS may suggest that a QCDR obtained permission from another QCDR to use their existing measure if there's measure overlap. Under special circumstances, duplicative concepts may be approved for one year under the condition that the QCDRs involved will work to address and resolve the duplication before the following performance period. Again, those are very individual and special circumstances and not a general rule that's typically followed. Usually, the more robust measure would be the one that's approved. And if there's duplicity with the MIPS quality measure, oftentimes the MIPS quality measure would be preferred as those measures are more broadly available and not restricted to only QCDRs.

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Finally, here are a few of the preferred measure types. Again, outcome-based measures are preferred over process-based measures. And these measures will focus on the health status of a patient, resulting from the care in which they received, and that the result may either be desirable or adverse. One type of outcome-based is the PRO-PM measure that are patient reported and the data is collected from the patient using a PROM tool. With these measures, the tools should be standardized, validated, broadly applicable, broadly available, and non-proprietary. And the last outcome is the Intermediate Outcomes. These measures look at

changes resulting from an intervention that leads to a long-term outcome where the Intermediate Outcomes actually leads to a desired health outcome. Another preferred measure type is Patient Experience. These measures are encouraged as they center around the patient's voice and encourage the patient's input when planning their care. And these measures may also help to improve the family and caregiver experiences as well.

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I will now turn it over to Marla Throckmorton with the PIMMS team who will continue providing some guidance and tips for submitting your measures.

>> **Marla Throckmorton, PIMMS**: Thanks, Stacy. Now, let's talk about the QCDR measure review process and tips for a successful submission.

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As you are preparing to submit your measure specifications using the QPP Self-Nomination Web Form, these are some of the things that we'd like for you to remember. One, as you enter all of your documentation into that web form, before you actually submit the measure to CMS, please make sure you review all measure specification components for accuracy. The QCDR measure specifications in their entirety must be submitted or should be submitted at the time of Self-Nomination. There are required fields that won't allow you to bypass them. This includes items that are required, such as testing, performance data, measure recommendations, and rationale. And then, of course, there are other required fields as well. Please note that all required borrowed measure specifications must also be submitted at the time of Self-Nomination. There are fewer fields that are required for a borrower due to the owner of that measure will determine the final measure specifications. Be sure to complete a spell check and grammar check because this information is publicly published on the QPP Resource Library. Substantive revisions won't be accepted after the close of Self-Nomination. Revisions are limited to only minor edits such as grammar, punctuation, and wordsmithing. QCDR measures can't be added after Self-Nomination closes. So for your QCDR to be able to support a QCDR

measure, it must be submitted during that Self-Nom period. MIPS quality measures, those clinical quality measures, and electronic clinical quality measures may be added after that September date. They can be added through early May of the next year. And then, please ensure that during the Self-Nomination period, you are checking your QPP Self-Nomination web form frequently in order to comply with all deadlines. The PIMMS team tries very hard to make sure that we're placing comments, reminding of deadlines, and trying to keep everyone aware of impending things that are due. And please remember if supporting QCDR measures in an MIPS Value Pathway or MVP that the measure must be self-nominated and submitted through the QCDR measures tab. And then if you are a borrower of an MVP QCDR measure, a borrower must also include written permission for use of that measure.

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Multiple strata denominators and patient populations. This is one area that we have noted there's been some issues and this is when you have performance rate submissions and data aggregation for measures with multiple strata denominators, patient populations, etc. There are several measures in the program that require the collection and submission of data for multiple populations. We refer to these as “multi-performance rate measures.” Multi-performance rate designation is based on what is required to be submitted to CMS to report on the measure. It should be noted that the QCDR may, and actually should, provide their clinicians with data from all of the strata, even if not required for submission to CMS for reporting. This will help the clinician to identify gaps in their clinical processes. It really helps if you review the specification to understand if it's a measure with multiple patient population submission strata with one performance rate or with multiple performance rates. And we're going to go through three different examples here in a moment.

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This graphic shows you how the questions are asked in the QPP Self-Nomination web form that we utilize for this analytic. The first column is the number of performance rates to be calculated and submitted. The second one is the performance rate descriptions, and then lastly you indicate

an overall performance rate. As after Self-Nomination, as we go through the finalization of measure specifications, you'll be sent a spreadsheet that gives you another opportunity to review what you input.

So let's talk through this a little bit for these multi-strata measures or multi-performance rate measures. There are two different options. One is that the QCDR aggregates the data and calculates the score, or the performance rate, before submission. This is when you have the single performance rate that you are submitting. Or the QCDR aggregates the data and then submits that data for then CMS to calculate the overall performance rate. In this example, there is one performance rate to be submitted. As you can see in that first column, that rate would be rate one, that top rate that's circled in the red. And then the overall performance rate would be the first performance rate, which the QCDR calculates and submits to CMS. But if you review this closer, this looks like it could actually be a multi-performance rate measure with two performance rates. So the first column should be a 2. That second column really should only include what's now denoted as Strata 2 and Strata 3, those male and female patients. And then that last column could be changed to a weighted average or simple average, which would be calculated by CMS. The goal is to not have specific performance rates called out for benchmarking. If they are truly weighted or simple average performance rate measures, that should be calculated by CMS.

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The first example that we're going to show is a focus on specific strata as the performance rate for the measure. The specified strata to be used for the required performance rate for CMS should be identified. For example, the overall MIPS Performance Rate may equal Performance Rate 2, for example. So you submit one performance rate, which then, as we talked about on the last slide, requires the performance data to be aggregated and calculated by the QCDR prior to submission.

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This example does show that the QCDR is going to calculate and submit the data for these two strata. And then they want CMS to select the second performance rate to be used for the benchmarking of this measure. The goal of this is to streamline information based upon the analytic so that it aligns in messaging across all MIPS quality measures. We want to make sure that CMS fully understands what is expected for this measure to be reported. Again, it would be important to share the strata-level data with the clinicians in order for them to know where improvements can be made in their practice.

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For the next two examples, this will show using a weighted average or a simple average of the available strata. For a weighted average, which is the sum of numerator values divided by the sum of denominator values, or if it is a simple average, it's the sum of performance rates divided by the number of performance rates. So you submit the measure data at each strata level, or performance rate, for CMS to calculate the overall performance rate. The number of performance rates to be calculated for a simple or weighted average have to equal or be greater than two performance rates. And then you would indicate, of course, which analytic you'd want to be used.

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So on this graphic, the number of performance rates to be calculated and submitted are two. But as we just talked about, you know, you could have six performance rates to be calculated and submitted. And then in that middle column, the description, you would have rate one through six. Here, of course, we're just showing rate one and two. And then in the overall performance rate, you would indicate here either simple average or weighted average, which would then be calculated by CMS from the strata data that has been submitted.

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Regarding ownership and eligibility of QCDR measures in the program, for a QCDR measure to be active within the program, it must be owned or co-owned by an approved QCDR that is active that year. So in the event that a QCDR decides to no longer participate and they really want their measure, or they think that their measure would be useful to remain in the program, or another QCDR that had borrowed the measure still wants to report on that measure, then the inactive QCDR may transfer measure ownership rights to an active MIPS-approved QCDR that is able to continue the support of the measure for that MIPS performance period. The new owner, or receiving QCDR, must be able to provide medical and measure expertise so that they will know how to amend and manage the measure. And honestly, the medical and measure expertise is evidenced by being an approved QCDR within the program because that is part of the Self-Nomination approval process. The new owner or receiving QCDR can then permit other QCDRs to borrow the measure as determined by the new owner. For borrowers, as we've spoken about before, permission must be granted at the time of Self-Nomination, so the borrowing QCDR has to include written proof of permission from the owning QCDR for CMS review and approval.

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There are instances where QCDR measures are not meeting the benchmarking thresholds for two consecutive periods, which means that the data being submitted to the MIPS program is insufficient in meeting the case minimum and volume thresholds required for benchmarking. But if a QCDR really believes that this measure is meaningful for their specialty, they want it to be able to continue in the program, even though they're not meeting this benchmarking threshold, then they can submit, or if they have gone through two cycles without achieving a benchmark, you're required to submit a participation plan in order for the measure to be considered. The participation plan must include the detailed plans and any changes to how they're going to encourage their eligible clinicians and groups to adopt and submit data on the low-reported QCDR measure for purposes of MIPS. Oftentimes, QCDRs will submit good data that shows good adoption or a large number of clinicians reporting the measure, but if that is just internal data, that does not go towards the MIPS benchmark. So those clinicians must be reporting to MIPS and establishing those benchmarks. The plan can include one or more of the

following, development of an education and communication plan for clinicians. They can actually amend or update the measure specification to encourage broader participation or even require reporting of that particular low-reported measure as a condition of reporting through the QCDR in order to enhance the reporting of that measure.

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QCDRs do not assign their own measure IDs to new and approved or existing measures. These are assigned systematically during the specification approval process by CMS. And the purpose of this is so that CMS can track and apply continuity to the measure ID, which then impacts benchmarking. So, for a new measure, a measure that's never been in the program, the first year that it's in the program, it will be assigned a new measure ID and have that first performance year as the year it was approved. For existing measures, though, that undergo some type of substantive change, a new measure ID may have to be assigned. And if a new measure ID does have to be assigned, then the first performance year is also updated to denote the year that it underwent the substantive change. Because this indicates that a new benchmark has to be established. Because the old measure ID and the benchmark is then essentially retired. Examples of reasons why new IDs may need to be assigned for existing measures, which this is not an all-inclusive list, but if there is something like a major analytic change, changing from inverse to non-inverse, proportional to ratio, adding a risk adjustment, you could be expanding the measure by adding a second quality action to the numerator. And then in some instances, there may be two or more QCDR measures that address a similar quality action. And those two measures or more may actually be combined to create a new measure. And then that new combined measure would actually have to receive a new measure ID and establish a new benchmark.

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Now let's talk about QCDR measure testing requirements.

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New QCDR measures, those measures that it's the first year in the program, at a minimum must have face validity prior to being Self-Nominated. After that, the QCDR measure has been through its first year in the program, so now it's being submitted for a subsequent performance period. The measure now must be fully developed and tested, which means complete testing results at the clinician level prior to submitting the QCDR measure. For a QCDR measure to be considered fully developed and fully tested, empirical validity, measure score reliability, patient/encounter-level (data element) testing, and feasibility must be completed.

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The role of testing performance measurement-- the role of testing in performance measurement. The reason proper testing analysis is so critical is that it makes sure that you have a feasible, reliable, and valid measure. Testing should be conducted during measure development, during alpha and beta testing. This testing enables developers to assess the strengths and weaknesses of the measure and then gives them the opportunity to mitigate those weaknesses of the measure. It assesses the reliability, validity, feasibility, usability, and scientific acceptability of measures to ensure they are meaningful. The purpose of this is to reduce provider reporting burden by making sure that they're not wasting their time collecting data on measures that aren't feasible or informative. This testing is an iterative process which occurs concurrently with measure specification development with the goal to yield more accurate and consistent data for performance program scoring such as the MIPS program that we're referring to.

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Validity confirms measure logic is not ambiguous and expected test patients fall in the correct populations. It determines whether data elements are aligned with national standards and checks calculated scores from automated extraction for accuracy. Validity also confirms the degree to which evidence, clinical judgment, and theory support interpretations of a measure performance score for MIPS. It's often appropriate to obtain stakeholder inputs at several points during the testing process, which includes that initial face validity at alpha testing, feasibility and burden

inputs at beta testing, and then other inputs as needed based on a review of overall results. For example, a QCDR measure would be valid if it clearly identifies the concept being evaluated, for example, that initial face validity. It can just demonstrate that performance on the quality construct is associated with a meaningful outcome or other indicators of processes related to the quality action, for example, construct or convergent validity. A valid QCDR measure can differentiate between disparate groups, for example, discriminate validity. Again, I just want to reiterate that new measures only require face validity for their initial year in the program. After that initial year, existing measures should be fully tested with empirical validity. And empirical validity is considered any type of validity beyond face validity.

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Measure reliability. Reliability evaluates whether the measured data elements produce the same results a high proportion of the time when assessed in the same population in the same time period or that the measure score is precise. The lack of reliability or precision demonstrates random error within a measure, which, of course, is what we're wanting to avoid. Conceptually, reliability is the measure of the ratio between signal to noise. Signal is the proportion of variability in a measure due to true differences in performance. So, of course, that is what we're aiming for with a good reliable measure. Noise is the proportion of variability in measure performance due to measurement error. And error can occur in a lot of different ways. Reliability testing of the measure score addresses the precision of measurement. Examples of reliability tests are signal-to-noise, temporal correlation, and random split-half correlation. Of course, again, this is not an all-inclusive list.

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Patient/encounter-level data element testing. This type of data element testing is what is required to meet the criteria for being a fully developed measure when we speak about being fully tested and fully developed. These patient/encounter-level data elements are the building blocks for a quality measure and should be assessed for either reliability or validity. And the program does allow either a reliability score for this data element testing or a validity score.

Validity testing of data elements, for example, criterion validity, verifies data elements against a reference criterion already determined to be valid. On the other hand, reliability testing of data elements refers to the repeatability of the testing findings. These types of tests are things such as inter-rater or intra-rater reliability in data abstractor studies, internal consistency for multi-item test or surveys, or test-retest for survey items such as measuring temporal reliability.

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Data element testing may be either empiric, new testing, or it could reference external previous testing, such as established data element libraries. Libraries, such as the CMS Data Element Library or the DEL, or the Electronic Clinical Quality Measure Data Element Repository, also known as the DERep. Data elements that have already been established over all the quality measures for a long time, such as age, does not have to be included in this data element testing.

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And finally, measure feasibility. This one is usually performed very early in the measure development process after the identification of the required data for measure calculation and before that specification is finalized. The importance of measure feasibility is the goal of making sure that all required data is retrievable without undue burden. It determines the extent to which developers can collect data and process it for their performance measurement without violation of patient confidentiality.

It estimates the cost or burden of data collection, data entry, and analysis, including the impact on clinician workflow, diagnostic thought processes, and patient-physician interaction. Feasibility also helps identify unintended consequences or identifies barriers that can occur during the implementation, abstraction of the data, measure calculation, and performance reporting.

If things are not feasible for a clinician, because a clinician workflow, for example, then the measure specification would need to be changed in order to make sure that it is feasible and the

clinician can actually report on the measure. Sometimes you will find low-reported measures may have feasibility issues, and that is why clinicians are choosing not to report that measure. As you test measure feasibility, this information may be suitable to support the validity of the data elements using systematic surveys or conducting focus groups, as we were just talking about on the prior slide.

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Let's look ahead into what the goals that CMS has for that transition to MIPS Value Pathways or MVPs. CMS has a goal of reducing clinician burden. And the way they want to do this is by focusing on measures that reduce the reporting burden such as using Administrative Claims Outcome Measures and moving to Digital Quality Measures or DQMs. Digital quality measures originate from sources of health information that are captured and can be transmitted electronically and via interoperable systems. eCQMs are a form of DQMs. CMS wants to align measures across programs where it's-- when it's at all appropriate. They want to emphasize the utilization of measures included in the Core Quality Measures Collaborative. And they also want to be able to emphasize quality measures that can be implemented the same or very similar across programs. By aligning measures across programs, those clinicians who do participate in multiple programs will have a decreased burden as they will not have to implement the same measure concept in multiple ways based upon the program. Going back to discussing that Digital Quality Measure, the goal is to utilize the integration of a new data interoperability standard, which is the Fast Healthcare Interoperability Resources, or FHIR, which is known as the FHIR data model.

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CMS' goal for MVP participation is that QCDRs, as well as qualified registries, must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. CMS' goal is to move away from siloed reporting by offering connected measures and activities across the four MIPS performance categories. These performance categories will incorporate a set of administrative claims-based quality measures that focus on population health, provide

data and feedback to clinicians, and enhance information provided to patients. The goal is to result in comparative performance data valuable to patients and caregivers in evaluating clinician performance and assisting them in making decisions about their care. The goal is to reduce the number of measure selection and reporting burden, which creates a streamlined approach to MIPS reporting while allowing for a more cohesive participation experience.

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For QCDRs that support MVPs, QCDRs, or again, qualified registries, must support all measures and improvement activities available in the MVP. The only exception to this is if an MVP includes several specialties, then a QCDR is only expected to support the measures that are pertinent to their specialty of their clinicians. Also, QCDR measures are only required, again required to be reported by the QCDR measure owner. Barring QCDRs may only support the measure if they have the appropriate permissions from the owner. So what impact will the transition to MVPs have on current QCDR measures? The way CMS will do this will be to review QCDR measures as a component of future MVPs. So these are the types of questions that are being asked. “Does the QCDR measure align with the current or future MVP topic?” “Does the QCDR measure complement improvement activities and cost measures?” And finally, “Does the QCDR measure align with the goal of keeping MVP stable year over year, again, as part of that goal to reduce clinician burden and reporting burden?”

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Requirements for QCDR measures to be included in an MVP. A QCDR measure must be fully tested and fully developed at the clinician level. This avoids inadvertent submission, calculation, or scoring issues later on after they've been added to an MVP. CMS needs to receive QCDR measure testing data for review by the end of the Self-Nomination period, no later than September 1 of the year. Our Self-Nomination period usually lasts from July 1 to September 1.

In the case of 2025 for the Self-Nomination for the performance year of 2026, September 1 falls on Labor Day. So I would anticipate the deadline to be September 2, 2025 and that testing data and the Self-Nomination of the measure has to be done by that end of Self-Nomination . QCDR measures must be active for one year prior to Self-Nomination to be considered for inclusion within a candidate MVP. If you are borrowing an MVP measure that is owned by another QCDR, you must Self-Nominate the QCDR measure as well as provide written permission to borrow that measure.

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I will now hand it back over to Stacy Sams with the PIMMS team to tell you about some great resources as you work through this QCDR measure development process. Thanks.

>> Stacy Sams, PIMMS: Thank you, Marla. So, as Marla mentioned, we'll just go over some resources that are available to you as you work through your Self-Nomination of QCDR measures and your measure development.

Next slide, please.

So prior to the opening of the Self-Nomination period, CMS does offer QCDR Measure Preview calls. And these calls, they give QCDRs an opportunity to review their measure concepts with CMS before Self-Nominating them. The preview calls begin next Monday, February 17, and go through May 30, and the last day to request a call is May 16. They are scheduled on a first-come, first-served basis so that we can accommodate as many requests as possible. And to request a call, please submit an email to the QCDRVendorSupport@gdit.com email. When you make a request, please provide multiple dates and times over a two-week period so we have more options to choose from. We also ask that you include all of the names and email addresses from your QCDR that you would like to attend the call. And then also, we ask that you submit your measure specifications at least seven days before the scheduled call. These can be submitted either in a single Word or Excel document. This just gives CMS

adequate time to review the measures and be prepared for the call so it can be more meaningful for you. These meetings do have to be rescheduled if the measure information is not received.

New for this year, we do have a QCDR measure specification template available if you choose to use that. This was provided with this month's support call materials, and we can also share it when you make your request if you would prefer to use that.

And we do understand that the measures that you want to discuss may be in their earlier stages of development. And for this reason, we just request that you provide the measure information that you have available at that time, and CMS doesn't expect that every measure specification will be fully developed. But the more information that you can provide, the better and more useful it'll be. And on these calls, CMS does not make measure decisions, the measures would still need to be submitted with your Self-Nomination to be considered for MIPS.

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So this slide provides some links to the Physician Fee Schedule Final Rule for Calendar Year 2025. Additionally, there's a Final Rule Fact Sheet that is available. And we also recommend that you utilize the Measure Management System Blueprint for measure development guidance. And this is contained within the measure management system hub. And there's a lot of information that may be useful for you.

Next slide, please.

Additional resources listed here are the Measure Development Plan and annual reports and a link to the Measure Management System. We also have links here to the Performance Year 2025 QCDR Measure Specifications and the 2025 MIPS Clinical Quality Measure Specifications and Supporting Documents.

Next slide, please.

This slide will share links to resources for Electronic Clinical Quality Improvement. These are educational resources, the Resource Center, and implementation-related information.

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And finally, with the transition and implementation of MVPs, this slide shares several links to multiple MVP resources for help and guidance in learning about this reporting option. You can learn about the implementation and the transition to MVPs, and we included an Explore MVPs Webpage.

Next slide, please.

So we've now reached the end of the presentation, And I'm going to turn it over to Hallie to lead us into the question-and-answer portion.

>> **Ketchum**: Thanks, Stacy. We can go to the next slide. So we're going to start the Q&A portion of the webinar. You can either ask questions through the Q&A box or through the webinar audio. To ask a question through the webinar audio, please raise your hand and we'll unmute your line so that you can speak. To submit a question anonymously via the Q&A box. Please click "send anonymously." Otherwise, all attendees will be able to view your question. And just as a reminder, you do need to have a working microphone to ask a question over the line. Now, we'll turn it back to Stacy to get us started with the Q&A.

>> **Stacy Sams, PIMMS**: Thanks, Hallie. Okay, we will get started with the question and answer. Our first question is, "is CMS accepting claims-based measures for MIPS?"

>> Colleen Jeffery, PIMMS: Hi, this is Colleen from the PIMMS team. It depends on how the measure is set up. We are accepting administrative claims-based measures as they pose no burden to the clinicians submitting them. We are not currently accepting measures that are solely for the Medicare Part B claims collection type. However, we do understand that there are

some folks who utilize claims for abstracting data and as part of their logic within the measures. And that is acceptable as long as it's also available to capture all-payer data.

>> **Stacy Sams, PIMMS**: Great, thank you, Colleen. The next question in the queue, "in reference to Dr. Kline's note about DQMs being eCQMs and other CQMs, would that include measures specified for registries?"

>> **Colleen Jeffery, PIMMS**: So this comment about Digital Quality Measures is really just working towards creating those measures that take as little manual work for abstraction and submission as possible. So, yes, for the most part, CQMs, or what historically were called registry measures, can fall into that DQM. Again, just looking for those measures that don't have the burden of needing manual medical record abstraction and such.

>> **Stacy Sams, PIMMS**: Great. Next question. "What recommendations do you have for specialties whose measures top out quickly and where gaps and performance or care are extremely difficult to find?"

>> **Colleen Jeffery, PIMMS**: So, this is a little bit more of a nuanced question and would really be on a case-by-case basis. We do understand that there are sometimes difficulties in finding areas within a specialty or sub-specialty that really show a large gap in care. So, we would just suggest, you know, reaching out for those preview calls or calls anytime during the year to see if you can get some time on the books with either the PIMMS team or PIMMS and CMS to kind of talk through any struggles and see if we can help to come up with some clinical topics that would make for successful quality measures.

>> **Stacy Sams, PIMMS**: Great. "Can you please remind us the difference between a denominator exclusion versus a denominator exception?"

>> **Colleen Jeffrey, PIMMS**: Sure. So the denominator exclusion is going to pull that patient out from the eligible patient population so they would not be considered part of that case minimum. So these would be patients who it is just not appropriate or not feasible to do

whatever the quality action is within the numerator, whereas a denominator exception allows kind of for that clinical judgment based upon the patient and their current circumstances. So there would be patients that are denominator eligible and may be appropriate for assessment of that quality action. But, again, there may be nuances or different aspects of the patient that as you're assessing, then may not make them appropriate for that clinical action.

And those would-- oh, sorry, go ahead, Dr. Green.

>> **Dr. Daniel Green, CMS**: I'm sorry, Colleen, I was going to just ask you to keep me honest, I mean, a tangible example would be somebody-- a patient who falls in the category of a mammogram. So she meets the criteria based on age and what have you. But perhaps she's had a mastectomy. So that would be an exception because she is in the denominator, but she'd be accepted out. But if I got that backwards, by all means, please correct me, Colleen.

>> **Colleen Jeffery, PIMMS**: Yep, nope, that could be looked at because you still want to make sure that the patient was looked at for a mammogram, but then there was a medical reason for not completing it. Whereas a denominator exclusion may be one that's in many of our measures is if the patient is in hospice, there's a lot of quality actions that would just be unnecessary for those patients and therefore they're just excluded from the denominator population.

>> **Stacy Sams, PIMMS**: Great. Thank you. The next question, "in developing oncology measures, cancer types, and their quality improvement efforts begin to lose their intent, value, and focus when bucketed. Whether it is outcomes, intermediate outcomes, PRO-PM, etc., grouping multiple cancer types into one measure in the vein of efficiency may have the opposite effect and will be difficult to implement as each cancer type patient may be addressed differently. And understanding this perspective, is the path of leaning into specially based MVPs of greater importance."

>> **Colleen Jeffery, PIMMS**: So, I can start with this one, but, Dr. Green, please feel free to jump in if you have anything to add. I think we're not necessarily stating that there-- that it's a

blanket statement that anything that's looking at a similar quality action with a different diagnosis necessarily has to be put together. I think that that process, especially when we get into areas where we have issues meeting case minimums with measures and being able to get benchmarks, and it is feasible to put some of these different measures together into one composite measure, you know, we really want to try to go towards that understanding that each submission criteria will likely have nuances with it. And obviously, you're going to treat different patients with different diagnoses, such as cancer, or what have you, they'll be treated differently. And so, all of those things are taken into consideration. There's just kind of multiple aspects going on and just, you know, kind of trying to find the middle ground for addressing all these different areas when putting these measures together.

>> **Dr. Daniel Green, CMS**: Thanks, Colleen. Our preference would be to have-- you know, again, if the concept is similar to have the measures, either as a multi-strata measure or what have you. But, again, it's going to, you know, it really is a variable in terms of the specific measure and condition that that's being covered. Because, you know, some things do make sense and some things, you know, clearly don't. I mean, for example, surgical site infection, potentially if you're talking about, you know, a contaminated case, a patient that's a victim of trauma, you know, versus a patient who's undergoing-- I won't say elected, but a planned breast biopsy, you know, we would expect the potential for wound infection, you know, would be different in those circumstances. So it really depends on the particular situation.

>> **Stacy Sams, PIMMS**: Great. Thank you, Dr. Green and Colleen. On to the next question, "for behavioral healthcare measures, it is not always feasible to expect outcomes to be manifest during the reporting calendar year. Clinicians measuring at the index visit occurring later in the reporting year may have insufficient time to record change as patient outcome. Example, assessing anxiety or trauma in October, the expectation of meaning, meaning change may be restrained by the calendar reporting year. What are the recommendations?"

>> **Colleen Jeffery, PIMMS**: Our recommendations for these types of measures where you're not necessarily expecting to see the outcome within, you know, six months or eight months or even 12 months, we can do what we call kind of an offset denominator period, which is where

we're going to have-- we're going to look for that index visit, but it may be outside of the performance period. So, for example, in some of our measures, such as looking for depression remission at 12 months, we look for that index visit in a different performance-- or in a different calendar year. Apologies. And then we would look for that assessment to occur during the performance period. So we do have-- same with functional outcome measures. We have a lot of those where the denominator eligible identification period is different than the calendar year period. But that's nuanced to, you know, the measure that you're working on. So, you know, those are types of things. Feel free to add in preview calls and such so we can work with you on kind of figuring out the best ways to set up those analytics.

>> **Stacy Sams, PIMMS**: Thank you, Colleen. The next question. "If we have existing approved QCDR measures created by us, and we would like to modify them to include unique PM, PNM, PE, and exclusion codes to be used to assist clients who adopt these measures and allow them to easily report them on claims. Would that require us to have a meeting with the PIMMS team before modifying and would those changes be considered substantive? The measures are second-year measures right now without same year or historical benchmarks?"

>> **Colleen Jeffery, PIMMS**: Right. So, I believe what you're asking for is for the creation of what we call HCPCS codes, or those quality data codes that are used for reporting purposes only. We generally do not create those for QCDR measures. However, I believe if that is something that you would want to look into, you may be able to work with CM to have those created within the HCPCS file that is done during the summer. However, we would have to go back and look into that as I--

>>**Dr. Daniel Green, CMS**: That's highly unlikely, Colleen.

>> **Colleen Jeffery, PIMMS**: Okay.

>> **Dr. Daniel Green, CMS:** With CM. They're-- I mean, you could conceivably go to the AMA and ask them to create a CPT-2 code, but the chances I think-- I don't want to speak for the AMA, but I believe the chances of that are very small. You'd be better off-- I mean, you'd be

better off having a-- getting the information some other way than necessarily a copy of the claim. The copy of the claim could put the patient in the denominator potentially. You could create your own code that they could append to whatever it is you're receiving to indicate the quality action. But I think expecting it to make it to the HCPCS tape for a QCDR measure I think is unlikely.

>> **Colleen Jeffery, PIMMS**: Thanks, Dr. Green.

>> **Stacy Sams, PIMMS**: Yep, thank you both. "If there is-- if there isn't an MVP currently that our profession fits into and several measures would like to be developed to form a new MVP, is there a special process for this?"

>> **Colleen Jeffery, PIMMS**: So I would say there's kind of a couple different routes that can be done. And some of them may need to be done concurrently. I would-- first off, I would start with Measure Preview calls. If you're looking to develop measures that you're hoping to put into an MVP or to form a different meaningful MVP, you know, we can definitely have those preview calls to talk out or talk through those concepts and kind of guide our thoughts from that perspective in terms of actually submitting a new MVP for consideration that is going to go through the Call for MVP Process, which I think is just something that happens year around. And that's when you fill out the submission form, which is on the QPP Resource Library for creating an MVP. And that would be down the process timeline when the measures are already developed and implemented within MIPS. But if you have further questions-- Dr. Green, I'm sorry, I see you coming off mute.

>> **Dr. Daniel Green, CMS**: I was just going to say, I mean, if you're interested in working with CMS to create a potential MVP in general with or without QCDR measures or maybe, you know, a combination thereof. We do have processes where we will meet with specialty societies and what have you, to review what measures could make up an MVP. I'm not sure the timeline for that right now. I don't know if you know Colleen, but if not, we could try to get that information for you.

>> **Colleen Jeffery, PIMMS**: Yeah, I would say I don't know all the timelines off the top of my head. But if you go to the MVP Resources out there on the QPP Resource Library, I know all of those timelines and submission criteria and templates for filling out, everything's out there. There's also a mailbox you can submit questions to specifically for MVPs and I know you can get answers from there.

>> **Stacy Sams, PIMMS**: Thank you. Next question. "Will CMS be reviewing all QCDR measures for potential inclusion in an MVP or is that something we need to submit as a recommendation during the MVP Maintenance Process."

>> **Colleen Jeffery, PIMMS**: So this is something as discussed during the presentation that we do look for kind of those supporting, you know, look at those QCDR measures that complement and support current cost measures and improvement activities and so on and so forth for addition into an MVP. As we move to sunset traditional MIPS, we will be looking for all of the measures to be found within MVPs. That said, this is not something that you need to submit separately per se as we are reviewing all of the QCDR measures. We are always thinking about which ones may be good for inclusion with an MVP. That said, there is the MVP Maintenance Process where you can submit-- where you can submit comment on if you believe certain QCDR should be added or removed from any of the current MVPs or candidate MVPs and again, all of that information and timelines and so forth will be on the QPP Resource Library MVP Site.

>> **Stacy Sams, PIMMS**: Thank you, Colleen. The final-- one other question. "Are QCDR measures contradictory to CMS' movement to DQMs?"

>> **Dr. Daniel Green, CMS**: So I would suggest not at all. I mean, we would love for folks to develop QCDR measures that can be electronically extracted from their clients' and clinicians' EHRs. So there's nothing saying that-- in fact, those would be even preferred. I can go as far as saying that. On the one hand. On the other hand, for us to be prescriptive and say we'll only consider Digital Quality Measures would put an additional burden and we were concerned would suppress QCDR measure development and submission. I mean, it could come to pass in

the future that that's a requirement. And certainly, as I mentioned, we would encourage that and we would appreciate that but, you know, also trying to recognize that not everyone has the technical capabilities of creating a formal DQM. And so that's how I'd answer that question.

>>**Ketchum**: Before we end the Q&A session, we just wanted to give a quick last call to see if anyone had any questions that they wanted answered today. As a reminder you can either type in your question through the Q&A box or you can raise your hand, and we'll unmute your line so you can ask your question over the phone. All right. Seeing no further questions, we will conclude today's Q&A portion of the webinar, so I'll turn it back to Chris Ferrante to conclude the call.

>> **Christopher Ferrante, CMS**: Thank you, Hallie. Yeah, I just wanted to touch on something that's really important that was mentioned earlier by Stacy. It's the QCDR Measure Preview calls. We love these here because we get to get in contact with clinical experts that show us their rationale for why or what kind of gap in care that they're trying to fill. So, we love to talk and have private calls with your teams about those. So those dates for the calls, for the QCDR Measure Preview calls are February 17, they start just next week. And the last ones will be on May 30. That's the last day to have a call. So with that being said, the last day to request a meeting is May 16, 2025. Just to give us time to set up the calls. Don't forget to include how many measures you want to go over so we can figure out how much time to allot for the call, as well as the contacts that you want included in the call. These calls are really important because they do a few things that have touched on a little bit, but they allow for CMS to preview measure concepts and offer constructive feedback prior to the Self-Nomination process. The calls can also include new QCDR measure concepts as well as perspective updates to existing QCDR measures. So we're pretty open about, you know, what the calls can-- if you have a rationale and it's worth talking about for measure development, please reach out to us and we'll do our best to accommodate you. I just want to remind everybody as well that QCDR measure decisions are not made on these calls. We will get back to you later on in a more formal manner, but it's really just a concept-based call. And also, preliminary measure concepts without fully developed measure specifications are also suitable for these calls. I just want to make that clear as well. So even measures that, you know, haven't been through very much testing at all, we're

still open to ideas and concepts for these calls. So, we're pretty open, like I said. And with that being said, I thank everybody for their time. I thank the whole PIMMS team and everybody at CMS for hosting the call and all the work that went into it. And thank you everybody for showing up and for your time and your attention. Bye, everyone. Thank you.