Quality Reporting Program

Support Contractor

The Life and Times of a Measure: An Overview of the Measure Development Process

Presentation Transcript

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Dianne Glymph: Hello, and welcome to today's webinar. Thank you for joining us today. My name is Dianne Glymph. I'm a Project Coordinator at the Support Contractor. Today, we will be providing an overview of the measure development process. Our speaker today will be Pam Rutherford who is a Project Manager for this program. Before I hand things over to Pam, I would just like to cover a few items. If you have not yet downloaded today's handouts, you can get them from our website at qualityreportingcenter.com. Just click on the events calendar, then today's event, and you should be able to download the slides from there. In addition, these slides are attached to the invitation you received for this presentation.

The learning objectives for this program are listed here on the slide. This program is being recorded. A transcript of today's presentation, including the questions and answers received in the chat box, and the audio portion of today's program will be posted at qualityreportingcenter.com at a later date. During the presentation if you have a question, please put that question in the chat box located on the left side of the screen, and one of our subject matter experts will respond. If your question does not get answered for some reason, please know that all questions and answers will be posted on the qualityreportingcenter.com website. Well, that does it for our housekeeping issues. Let's start the presentation. Pam?

Pam Rutherford: Good day to everyone and thanks for joining us. As Dianne stated today, we're going to cover the measure development process. So, how does a measure end up

being a measure in this program? Well, let's look at the basics on how this happens because there is so much information on this subject that if you did a web search, you would come back with tons of information, and it's easy to find yourself overwhelmed. For example, one of the great documents on this subject is the Blueprint for the CMS Measure Management System but that one resource is 379 pages long. So, it may take you a little bit of time to get through it. Now, our goal today will be to summarize and streamline this information for you. So, we will not be at all going into detail, just giving you the idea, an overview if you will, of how a measure is developed.

From a global perspective measure development creates, tests, and put forth measures for various programs. CMS developed the Measures Management System, or MMS, as a standardized system for developing and maintaining quality measures similar to how a tree grows from a seed into a tree that may bear fruit.

Now, there are some general principles that guide measure development, and these principles are used throughout the measure development process. These principles serve as an overarching guideline for measure development that meet the standards and the rigorous expectation of a meaningful, valid, and useful measure. To make a very short statement about measures is that they should focus on what is best for patients. After all, that's what it's all about, but accomplished how? Well, measures should explicitly align with meaningful measures and its goals and objectives. Measures should also align with other stakeholders such as CMS, other Federal partners, and private payers. They should address a performance gap where there is known variation in performance and be based on collaboration among measure developers and share best practices. They should align around patient-centered outcomes that span across clinical settings which may require different versions of the same measure. For example, different cohorts, or groups, but the same numerator, and it's important to test each of these settings' specific version for reliability and validity.

Measures should also be focused on outcomes including patient-reported outcomes, safety, patient experience, care coordination, appropriate use, and efficiency, and cost. They should identify and eliminate disparities in the delivery of care and certainly avoid unintended consequences of measure implementation, including overuse and underuse of care. To align with meaningful measures, which we will discuss in a moment, measures should strive to reduce clinician burden in reporting measures. And, lastly, measures need to be meaningful to patients, caregivers, and providers.

So, we know the principles of measure development, so why does CMS have measures and quality reporting programs? Well, at CMS, the top priority is putting the patient first, with the patient always being at the center. CMS' strategic goals support the patient and overall patient experience, and CMS' goals

are to improve the CMS customer experience, usher in an era of state flexibility and local leadership, support innovative approaches to improve quality, accessibility, and affordability, and empower patients and clinicians to make decisions about their healthcare. Specifically, CMS wants to increase the number of satisfied customers, whether that be clinicians, providers, or health plans, while decreasing hours and dollars providers spend. CMS collaborated with stakeholders to develop the Meaningful Measures Initiative which is a comprehensive approach to focus on core issues and measurement areas which are more patient-centric and vital to providing high quality care and improving patient outcomes. Having said that, let's talk about meaningful measures.

In October of 2017 CMS introduced the Patients Over Paperwork Initiative to stress the agency's commitment toward patient-centered care and improving outcomes while concurrently reducing burden for clinicians and providers. The Patients Over Paperwork Initiative include several major tasks aimed at reducing obstacles that get in the way of this critical time spent with patients, one of which is reducing regulatory burden. CMS also introduced the Meaningful Measures Initiative which achieves goals while minimizing burden.

So, how do meaningful measure areas relate to existing CMS' programs? You can see the six meaningful measure areas and how this impacts the other areas. This framework is intended to increase alignment of measures across CMS programs, and, to the extent possible, across public and private initiatives. This can be achieved by pointing to high-priority areas where there may be gaps and available quality measures to help guide our effort to develop and implement quality measures to fill those gaps. It is important that clinicians and providers have the time to focus on their patients and improve quality of care that is meaningful to them instead of just reporting or doing paperwork. So, by prioritizing the use of outcome measures through high-priority process measures, CMS will continue to seek and obtain those core outcomes and priority outcomes. With this framework, the objective allows to better distinguish quality priorities. However, it does not in and of itself create any new measures or new meaningful measure sets. The idea is that CMS will use these goals, objectives, and framework to apply to all of our measures and programs to ensure all of the measures in our program are most meaningful.

Specifically related to this program, the Meaningful Measures Initiative, as it relates to minimizing cost includes, the facility information collection burden related cost and the burden associated with the submitting and reporting of quality measures to CMS, the facility cost associated with participating in multiple quality programs and tracking multiple similar or duplicative measures within or across those programs, the cost to CMS associated with the program oversight of the measure including the measure maintenance and public display, and lastly, the facility cost associated with compliance with other Federal and/or State regulations.

These proposals also reflect our efforts to improve the usefulness of the data that is publicly reported. CMS' goal is to improve the usefulness and usability of CMS' quality program data by streamlining how facilities are reporting and accessing data while maintaining or improving consumer understanding of the data publicly reported on a Compare website. This framework will allow facilities and patients to continue to obtain meaningful information about facility performance and incentivize quality improvement while also streamlining the measure set to reduce duplicative measures and program complexity so that the cost associated with participating in the program do not outweigh the benefits of improving beneficiary care.

Historically, process measures have outnumbered outcome measures. Just like a trellis supporting a plant during growth, CMS is moving towards developing and implementing more outcome measures moving forward. CMS is rebalancing the portfolio of measures to contain more outcome measures and fewer process measures with the goal of better addressing performance gaps in the Meaningful Measures Initiative.

So, how does a measure grow from a seed to a full-grown tree? And how does it go through the process of becoming a measure in this program?

Well, I mentioned at the beginning of the webinar that CMS' approach to measure development, known as the Measure Management System, consists of a set of processes and decision criteria that CMS-funded measure developers follow in the development, implementation, and maintenance of quality measures. Standardized processes include quality measure reviews by Technical Expert Panels, or TEP, online posting for public comment, and rigorous testing of measures before they are submitted to CMS for approval. Before we get too far in this standardized process, let me mention some groups that will be forthcoming on the subsequent slides. By discussing them first, it will make more sense as we proceed.

The National Quality Forum, or NQF for short, has convened annually since 2011 bringing together more than 135 healthcare leaders and experts from over 90 private and public sector organizations to provide recommendations on the high-impact measures that will improve health and healthcare. Through this multi-disciplinary group of experts, they will work together to vote on a recommendation of a measure, and from there a report is drafted by NQF that is made available for public comment. The NQF will also provide input on the Measures Under Consideration which we will discuss in more detail shortly. Now, the Measures Application Partnership, or MAP, is a multi-stakeholder partnership which consists of three main workgroups including clinicians, post-acute care, long-term care, and hospitals. All MAP meetings are open to the public. Reports and other materials are made available on NQF's website, and public comment are sought on MAP recommendations and, like CMS, the MAP

reviews and considers every comment received. The MAP, through that report drafted by NQF, then makes a recommendation to the Secretary of Health and Human Services. CMS definitely considers those recommendations; however, it is important to note that they are not obligated to completely take those recommendations. They are, in fact, just recommendations, and CMS can choose to either put a measure in the program that has not been recommended or vice versa. The NQF endorsement is not required for measures to be accepted into this program.

Now that we have some background information, let's get back to the process. How are those measures developed? This is a visual representation of the process. In the very center of this diagram you can see the Conceptualization. This is the beginning in this phase. These phases are intertwined, and you will begin to see this as we proceed. So, let's begin to break this down.

In the first phase of the measure development, Conceptualization, you are looking to bring a concept forth. Let's take a look at some of the key aspects of this phase. You can see from the diagram that there's a lot going on, and we'll go through some of the logistics here and then break it down even further. Some of you may not be familiar with the terms, so let me give you a little bit of an overview of these first. Information Gathering. An environmental scan is conducted to determine a list of potential measures that will support the selected measure topic. Environmental scans are analyses based on survey and collected information regarding environmental factors that impact the definition and development of quality measures. There will also be a gap analysis to identify whether any of the potential measures could support the selected measurement topic or if any existed measures could be re-purposed or harmonized to meet the same objective. Develop business cases to describe how and why new measures need to be created, as well as, why some measures may need to be re-purposed to support one or more of the quality programs. The business cases help inform the burden of the measure. What are the benefits of the measure to patients and their families? What is the cost and time in resources to implement the measures on clinicians or patients and families? If we're trying to gather survey data, how much time will it take to collect the data and report the data? And then, how much time will it take to analyze the data in the clinical practice or at CMS? What changes could result from the implementation of this measure? You would want the benefit of the measure to far outweigh the burden of the collection of data for the measure. This should demonstrate why the measure is needed and how it furthers the aims and objectives of CMS, the values of the measures and why it is best balanced of cost, benefits, and risks, the viability of the measure as it relates to healthcare sectors' ability to respond, realistic and affordable cost, and sufficient capability within the system to implement the measure. In this beginning phase, you will initiate stakeholder input and convene a Technical Expert Panel, or T-E-P, or TEP, composed of professionals with a professional backgrounds and expertise, as well as, patients and other stakeholders, to assess

the list of potential measures and make recommendations on which one or ones to develop. These experts will help develop the business case. Please note, this is not linear, and the information obtained from this will inform the choice of collection method for the measure. And, lastly, submit a filtered list of potential measures to CMS to select measure development priorities and offer public comment. Let's see if I can address the "What," "How," and "Who" of all these different phases.

The "What" of this first phase in the process is the Concept. Again, in this first step, one should consider whether the concept is important. You have a great idea, now what? Should it be measured? Can it be measured? Who wants to know? This is the most important step because the developers will have to use this concept to govern everything they do moving forward with the measure. They will need to present evidence, whether it's from literature, providers, patients or what have you. They will need to identify how they can measure the concept and can measuring the concept actually be used for improvement. How is this all accomplished in the first phase? The evidence-base is established through literature reviews, clinical practice guidelines, and interviews with subject matter experts and stakeholder organizations. Sometimes CMS posts a call for measures as part of the environmental scan which we just discussed. Developers then develop a business case which they will have to defend. Here is where each measure is evaluated. There must be consideration of the prevalence of a condition in the Medicare population and develop cost statistics. In this way measure developers will relate the cost of implementing the measure against savings that result from implementing it which is a necessary component that relates back to the Meaningful Measures Initiative. The next step is to develop an initial list of the measures based on the results of the previous steps. This list may consist of adopted, adapted, new measures, or measure concepts. This list will be reviewed and narrowed down to create the list of potential measures that might be included in quality reporting programs. The "Who." The TEP, T-E-P, contribute directions and input. We previously discussed that the TEP is a group of stakeholders and experts. There are a number of stakeholder groups that develop quality measures. CMS, of course, develops measures, as do some of our Federal partners. There are numerous organizations involved in measure development.

Moving on to the next step in the process, Measure Specification. This phase will provide the comprehensive details that allow the measures to be collected and implemented consistently, reliably, and effectively. The proposed measures are posted online for public review and comments. These various measure components may be expanded upon such as population, numerator, denominator, exclusions, exceptions, and calculation algorithms. Studies are performed which will further refine each case. Now, stakeholder input is, once again, a huge part of this aspect. Any comments received during the public comment period will be reviewed and taken into consideration by the measure developer and the TEP and will often result in revisions to the measure specifications.

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During the second stage of the CMS lifecycle measure specifications, there is the "What." This identifies the population that is to be measured. For example, patients receiving a screening coloscopy without biopsy or polypectomy. At this point there needs to be a decision on how that measure should be reported. Should we use claims data, chart-abstracted data, or any other avenues of submission? Also, to consider, are there measures that could harmonize with this measure? As far as the "How," measure developers must draft precise technical specifications including very clear definitions of the numerator and the denominator. There's also the defining of the data source. If the measure is calculated from more than one data source, the developers create detailed specifications for each data source. They collect evidence so that the results calculated from the different data sources are comparable. Construction of data collection protocols define key terms, data elements, level of analysis, sampling, risk adjustment, scoring, and develop any needed algorithms. The "Who" are the measure developers and any of the various organizations that are actively involved in measure develop. So, let's move on to the next phase, Testing.

The Measure Testing aspect is a comprehensive testing to evaluate whether the proposed measures will support the program successfully. The overall steps include develop and execute alpha and beta test plans to determine whether the measures can be reported, and the data supports the evaluation of quality and targeted programs, and we'll discuss this in a little bit more in just a moment. Again, any documentation of the results will be posted for public review and comment. Once again, the TEP is involved to review test results and public comments to determine if quality measures support the intended quality programs adequately.

During the third stage, the "What," is the data that is collected. The "How" is the testing, both formative and field testing, are completed to ensure the valid and reliable implementation of the measure across organizations. The testing phase generates empirical evidence to assess the strengths and weaknesses against five criteria. These criteria are importance, scientific acceptability, feasibility, usability, and related or competing measures. In this phase there will be development of the testing work plan which is going to include alpha and beta testing. This stage, Testing, builds on previous Specifications stage. Alpha test, also called formative test, are a limited scope since they usually occur before detailed specifications are fully developed. Alpha testing often focuses on feasibility. Here the measure developers are determining if individual data elements are available and if the form in which they exist is consistent with the intent of the measure. Alpha testing may actually occur as early as the Information Gathering step and is repeated during the development of the measure specifications ensuring that the measure is as solid as possible before we ask clinicians to pilot the measure in the field. After the testing ends, the results are analyzed with a return to the Specifications phase or even the Conceptualization phase to rework the measure before testing it again. This would

entail re-engaging with stakeholders. The beta testing, also called the field testing, generally occurs after the initial technical specifications have been developed and is usually larger in scope than the alpha testing. In addition to gathering further information about feasibility, beta tests serve as the primary means to assess scientific acceptability and usability of a measure. Beta testing, which is also referred as a field testing, generally occurs after the initial specifications have been developed, and it is usually on a larger scale than alpha testing. The primary purpose for beta testing is to understand the usability of the measure and to test the scientific acceptability of the measure. Once all the data is gathered, the measure developer conducts a series of analyses to characterize the feasibility, integrity, and phase validity of the measure. The measure developer may need to modify the measure specifications, data collection instructions, and calculation of measure results based on analysis of the testing results. The "Who," measure developers, may also involve you if you are at a research facility and the TEP especially if changes in refinement are made. It is crucial to consult the TEP to see if they have any recommendations. Additionally, pilot sites; these are facilities that take part in the alpha and beta testing.

Measure Implementations supports the rollout to the healthcare providers who will collect and report the new measures. The Measure Implementation phase is the beginning of the CMS rulemaking process. Stakeholder engagement is critical here. Work groups are assembled, and public comment periods occur at this point in the development process. Measures are placed on the MUC List. MUC stands for Measures Under Consideration. I'll go into a little more detail on some of the aspects you see here on the next slide. The implementation process for measures is meant to be transparent and open to the public for comments and questions. Comments and feedback can be submitted through the pre-rulemaking or rulemaking process or through ad hoc comment processes. After reviewing the comments, CMS will decide whether or not the proposed measure should be implemented in the program. If so, a Final Rule will be published specifying the measure, the program the measure will be implemented in, and the implementation date. So, now let's look at this from our "What," "How," and "Who" perspective.

Up to this point, the measure has been under development, MUD for short. Now, we find ourselves here at the Measure Implementation phase where the measure is fully developed. During this implementation phase, the "What" is simply the possible adoption of the measure. The "How" is collecting the list of measures to be considered. The list of Measures Under Consideration are referred to as the MUC List. So, the gist of this you would go from the MUD, M-U-D, to the MUC, M-U-C. By December 1 of each year, CMS makes this MUC List available to the public. Then, by February 1, the NQF will provide its input regarding the selection of those measures. Now, a few things could happen, and this is the part of the "Who." The NQF may endorse a measure, and CMS may decide that it's going to include that measure in the current rulemaking cycle. Or, CMS might

decide that this isn't the right time, and they might choose to propose or adopt that measure in subsequent rulemaking cycles. Or, CMS might decide that this really isn't really the right measure at all and never propose the measure for inclusion in a quality reporting program. But, what if the NQF decides that it doesn't want to endorse a measure? Well, CMS must consider that recommendation. If CMS decides that it wants to propose the measure despite lack of NQF endorsement, then CMS must publish its rationale.

The final phase with this diagram is the Measure Use, Continuing Evaluation, and Maintenance phase. This phase monitors and measures the use of the quality measures to ensure that they continue to support the quality programs they were designed to support, identify opportunities to tweak, or re-purpose measures to improve reporting an increase of the value of the quality program measurement results. Let's take a look at these tasks.

In the final phase of Measure Use, Continuing Evaluation, and Maintenance, the developer wants to know is the measure working? The program must always monitor the performance of measures, respond to ongoing feedback, and continuously scan the environment which is the "What." The "How." Every measure undergoes an annual update which is limited review of the Measure Specifications and also includes a review of the reliability and validity of the data elements. So, an environmental scan is completed, a TEP might be convened, and a business case is updated. NQF also conducts a three-year maintenance review. This allows CMS an opportunity to review the findings and recommendations prior to submission to the NQF. Oh, this is also the time that CMS will assess for related or competing measures and efforts can be made to harmonize Measure Specifications with other measures. A measure may have various potential outcomes based on the evaluations. They can retire. This applies only to measures owned by CMS. CMS will not continue to maintain these measures, cease to collect, or report the measures indefinitely. They can retain them. Keep the measure active with its current specifications and minor changes. Revise them. Update the measures current specifications to reflect new information. Suspend them. Cease to report a measure. Remove them. A measure is no longer included in a particular CMS program set. The "Who" continues to be the measure developers, TEP, and other associations because, remember, these evaluations are constant.

As we have discovered here today, developing a measure is a complex and involved process, and many of the phases take significant time to ensure a quality product. This diagram is illustrative of the complexity and timeframe needed to develop a measure. The end product of measure development is precisely specified, valid, reliable, and clinically significant measure that is directly linked to the CMS quality goals. This image on the slide shows a high-level view of the major tasks and timelines involved in developing measures from the time of the initial measure development contract award through measure implementation and

maintenance. Although the diagram shows the five phases of the measure lifecycle in a linear and sub-sequential fashion, measure developers have some flexibility to adjust the sequence or carry out steps concurrently and repetitively. As such, this is only an estimate of the possible timeline of the measure development lifecycle.

Measures may be classified according to a variety of schemes including meaningful measurement, CMS pre-rulemaking, types, or NQF submission types. Just like there are many classifications of trees, there are different classifications of measures. Let's take a look at that.

On the next two slides are the measure classifications. A Composite Measure is a measure that contains two or more individual measures resulting in a single measure and a single score. Composite Measures may be composed of one or more process measures and/or one or more outcome measures. Cost or Resource Measures are broadly applicable and comparable measures of health-service counts. A Resource Measure counts the frequency of defined health system resources; some may further apply a dollar amount to each unit of resource. An Efficiency Measure is a measure concerning the cost of care associated with a specified level of health outcome. Efficiency Measures are not typically part of this program, as measures for this program go through rulemaking. An Outcome Measure assesses the results of healthcare that are experienced by patients: clinical events, recovery and health status, experiences in the health system, and efficiency and cost.

A Patient-Reported Outcome Measure is a measure that focuses on patient's report concerning observations of and participation in healthcare. A Process Measure focuses on steps that should be followed to provide good care. There should be a scientific basis for believing that this process, when well executed, will increase the probability of achieving a desired outcome. Lastly, we have the Structural Measure which is a measure that assesses features of a healthcare organization or clinician relevant to its capacity to provide healthcare.

We know the types of measures are different trees and the process for development or lifecycle of the trees. How does CMS decide what measures is implemented into the program? How does CMS decide, kind of, of what fruits to be harvested? So, let's tie in some of what we've talked about already and elaborate on how the measures are implemented into a program.

CMS uses the following decision criteria throughout the measure development cycle to ensure a measure meets the applicable standards before moving to the next stage. Essentially, aspects of this decision-making are the importance to measure and report including analysis of opportunities for improvement such as reducing variability in comparison groups or disparities in healthcare related to race, ethnicity, age, or other classifications. Scientific acceptability including

analysis of reliability, validity, and exclusion appropriateness. Feasibility including evaluation of reported cost or perceived burden, frequency of missing data, and description of data availability. Usability, that's included planned analysis to demonstrate that the measure is meaningful and useful to the target audience. This may be accomplished by the TEP reviewing the measure results such as a means and detectable differences, dispersion of comparison groups, and more. More formal testing, if requested by CMS, may require assessment via structured surveys or focus groups to evaluate the usability of the measure.

To increase the transparency, the Affordable Care Act required the establishment of a pre-rulemaking process for the selection of healthcare quality measures. Pre-rulemaking was a significant change as it marked the first time the Federal Government collaborated with public and private sectors in advance of regulatory rulemaking with regard to the selection of performance measures. There is a subset of programs that do not go through the pre-rulemaking process but do go through rulemaking. There is also an additional subset of programs that do not go through rulemaking at all. They may go through rulemaking for the initial start of the program or when making major changes, but minor changes would not go through pre-rulemaking. With this process, CMS issues a call letter to solicit measures which are then submitted and go through the clearance process. A measure may go to the M-A-P, or MAP, for review and decision and for public comment. CMS then issues a final letter rather then go through the Final Rule. Now, we're not going to explore that aspect today, because as we know with this program, any additions or changes to the program follow the rulemaking process.

This is a snapshot of the pre-rulemaking process involved in measure selection for this program. As part of the CMS pre-rulemaking process, the Measures Under Consideration List, or the MUC List, is issued by December 1. Recall, we discussed this on a previous slide. Developers submit measures for CMS to consider including in certain CMS programs. Early, in each Calendar Year, through a call for quality and efficiency measures, CMS begins the annual pre-rulemaking cycle of collecting and compiling the MUC List, usually from February through May. Stakeholders submitting measures include CMS and healthcare and other professional groups. Following submission, the pre-rulemaking process includes review and clearance of candidate measures within CMS and the Department of Health and Human Services and provides the opportunity for multi-stakeholder groups to offer input. The NQF convenes the measures application partnership, or MAP, in December of each year to review and comment on the measures proposed on the annual MUC List. Annually, the MAP workgroups and the coordinating committee meets to provide program-specific recommendations by February 1.

For measures to be implemented in a program, they must go through the rulemaking process. It's pretty straight-forward in that each program publishes a Proposed Rule and puts it out there on the Federal Register. They then have a

specified public comment period of 60 days for the public to submit comments or letters to CMS. Then CMS will use those comments and letters to make decisions and make changes in the Final Rule. There have definitely been times when CMS has changed the proposals and made changes to the Proposed Rule because of the public comments that were given. So, remember to comment this summer when the next Proposed Rule comes out. In the Final Rule CMS will make sure that all of the public comments are addressed in that Final Rule.

For those of you who are new to the program, let me just give you a very simplified version of the rule process. Each July, after months of evaluation, research, and writing the Proposed Rule is published. From the Proposed Rule release date, the public has 60 days to submit comments regarding the proposed changes to the program. Then, in November, after reviewing and considering all your comments, the Final Rule is published. With every Final Rule you have the most current information for guidance in this program. That is a relatively very brief synopsis of the measure development. Again, there are many resources available to you. Well, that's all I have for you today. I hope this overview has given you an idea of the measure development process. As stated at the beginning, there are a lot of resources on this subject. We do have a resource list at the end of the slide pack should you need them. All right, Dianne? Back to you.

Dianne Glymph: Thanks Pam. We appreciate your joining us today. All the questions and answers from the chat box are posted to our website qualityreportingcenter.com.

And, as Pam mentioned, if you're interested in digging a litter deeper into measure creation and development, there are three reference slides at the very end of this presentation with resources that shed even more light on this subject. I'm going to turn things back over to our host to go over the CE process. Thank you everyone and enjoy the rest of your day.