CENTERS FOR MEDICARE & MEDICAID SERVICES

CMS Measures Management System
Blueprint QuickStart Guide

July 2024

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Introduction

ABOUT THE QUICKSTART

Designed with both experienced and novice measure developers in mind, the CMS MMS Blueprint Measure Lifecycle QuickStart Guide (QuickStart) provides a start-to-finish overview of quality measure ⓘ development, implementation, and maintenance ⓘ steps and processes. Each section includes information about important steps associated with a given stage of the Measure Lifecycle, along with links to additional resources, templates, and references to *CMS MMS Hub* (*MMS Hub*) pages and supplemental materials of the Blueprint content. Terms indicated with an information (ⓘ)-icon in this document show additional information when you hover over the text.

The QuickStart provides tables, checklists, and procedural graphics as a tool to guide measure developers through the mechanics of measure development, implementation, and maintenance. For a more comprehensive overview, visit the Blueprint content on the *MMS Hub*. To take a deeper dive into specific topics, view the *Blueprint supplemental materials*.

CMS PRIORITIES & MEANINGFUL MEASURES

In nearly every setting of care, CMS is moving from paying for services to paying for value, not volume. CMS goal is to foster value by promoting the highest quality, safety, and care experience with the most affordable, cost-efficient service possible for Americans. To do this, CMS develops quality measures (measures) addressing health care priorities and goals and aligning with patient needs. Each measure focuses on a different aspect of health care, such as processes, patient health outcomes, patient perceptions, and organizational structure and/or systems.

The purpose of CMS measures is two-fold. First, measures promote quality and reduce waste in health care by incentivizing good performance and disincentivizing poor performance through public reporting and pay-for-reporting programs, and by allowing CMS and participating measured entities ⓘ to track performance over time. Secondly, they improve patient decision-making by providing data through public reporting (e.g., Star Rating) to help patients, families, and caregivers make informed decisions about where to seek care that is not just based on cost. Given this critical role, measures must be meaningful, robust,[1] valid, feasible, based in scientific evidence, and well tested to ensure the measures do not lead to unintended negative consequences or burden for patients or measured entities.

CMS launched the comprehensive Meaningful Measures Initiative in 2017, which identifies high priority areas for quality measurement and improvement. The purpose of this initiative is to improve outcomes for patients, their families, and measured entities while also reducing burden and moving payment toward value through focusing everyone's efforts on the same quality areas. The Meaningful Measures Initiative also helps to identify and close important gap areas of measures, align measures across the continuum of care and across payors, and spur innovation in new types of measures such as patient-reported measures and digital measures.

[1] Throughout the document, "robust" refers to measures with the most vigorous quality action or guidance or as a descriptor to describe strong, vigorous, or thoroughly vetted components of a measure.

MEASURE LIFECYCLE

The Measure Lifecycle ensures measure developers create precisely specified, valid, reliable, and significant measures that directly link to CMS quality goals. The Measure Lifecycle graphic, Figure 1, provides a high-level view of the major tasks involved in developing measures from the initial concept through measure implementation and maintenance. While the stages follow a general sequence, the process is highly iterative and allows developers the flexibility to carry out stages concurrently. Additionally, measure developers perform cross-cutting activities such as information gathering, interested party engagement, and feasibility evaluation throughout the Measure Lifecycle.

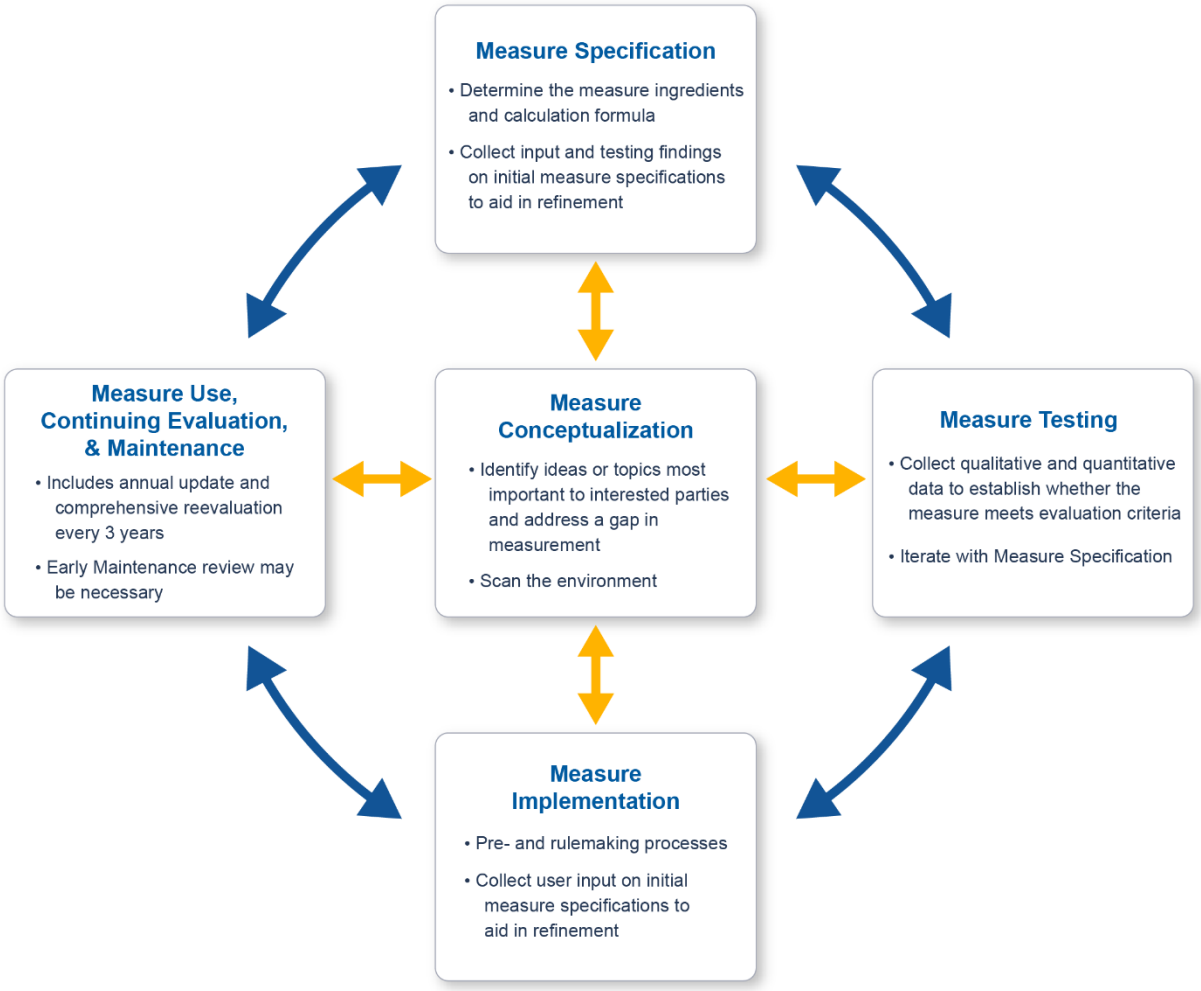

Figure 1. Key activities carried out by measure developers during the Measure Lifecycle.

EVALUATION CRITERIA

Measure evaluation is not a single step in the Measure Lifecycle. Rather, measure developers should apply evaluation criteria throughout the development, implementation, and maintenance processes to identify weaknesses in the justification and provide an opportunity to revise and strengthen the measure. The more effectively the measure properties meet evaluation criteria, the more likely the measure will be robust and meaningful.

The evaluation criteria are

- Importance ⓘ to measure and report: evidence and performance gaps
- Scientific acceptability ⓘ of measure properties: reliability ⓘ and validity ⓘ
- Feasibility
- Usability and use ⓘ.

These criteria align with the CMS consensus-based entity (CBE) evaluation criteria. Although CMS CBE endorsement is not a requirement for use of a measure in a CMS program, CMS encourages seeking endorsement given that endorsement indicates a level of rigor in testing and evidence that CMS is seeking for its measures.

Further, CMS expects development and testing of measures that do not seek CMS CBE endorsement to be in accordance with these evaluation criteria.

For more information on the CMS CBE evaluation criteria, see the Partnership for Quality Measurement (PQM) Endorsement and Maintenance (E&M) webpage.

Measure Conceptualization

The key components of measure conceptualization are information gathering and business case development.

INFORMATION GATHERING

DESCRIPTION Information gathering includes an environmental scan (e.g., review of literature, search for clinical practice guidelines and existing measures, input from experts, and other related activities) and empirical data analysis. These activities yield information that will guide the prioritization of topics or conditions, gap analysis, business case development, and compilation of related and competing measures.

PURPOSE Information gathering demonstrates the existence of a performance or measurement gap related to the topic of interest; it helps demonstrate measure importance and explore feasibility. This process should yield quality goals, strength of scientific evidence pertinent to the topics/conditions, and information with which to build a business case. It will also produce evidence of general agreement or conflicting views on the quality issues surrounding the topics/conditions.

INFORMATION GATHERING CHECKLIST

- ☐ Identify the health care quality issue and determine its priority area
- ☐ Conduct an environmental scan
- ☐ Analyze empirical data, as appropriate
- ☐ Evaluate information collected during the environmental scan and empirical data analysis
- ☐ Conduct a measurement gap analysis to identify areas for new measure development
- ☐ Justify the creation of new measures
- ☐ Apply measure evaluation criteria
- ☐ Prepare an initial list of measures or measure topics

HOW TO PERFORM AN ENVIRONMENTAL SCAN:

- Develop a series of unambiguous, structured questions to limit the search to a specific problem set.
- Determine the framework for relevant work, including literature databases and search engines, keywords and phrases, inclusion and exclusion criteria, and domain experts.

- Assess the literature using qualitative techniques and quantitative metrics such as impact (e.g., number of times a paper is cited, number of page views), innovativeness, consistency with other works on the topic, recency of citations used in the work, seminality/originality, and quality of writing.
- Qualitatively evaluate and summarize the evidence. Evaluate the effectiveness and value of the data sources, sample sizes, data collection methods, statistical methods, periods, and research findings.
- Interpret findings by evaluating the similarities and differences among the findings; then, draw conclusions to inform data collection and analyses.
- Refine research questions and develop hypotheses. Generate a general analysis plan, including data sources and estimation procedures.

EXAMPLES OF INFORMATION SOURCES

- ☐ CMS Measures Inventory Tool (CMIT)
- ☐ Environmental Scan Support Tool (ESST)
- ☐ De Novo Measure Scan (DNMS)
- ☐ Agency for Healthcare Research and Quality Clinical Decision Support

BUSINESS CASE DEVELOPMENT

DESCRIPTION The business case documents the information needed to assess the anticipated benefits of a measure against the resources and costs required to develop and implement a measure (burdens vs benefits).

PURPOSE Facilitates decision-making about whether to invest resources in the development and implementation of a potential measure; helps demonstrate usability, importance, and feasibility.

The measure developer initiates a business case early in measure conceptualization, updates and enhances it throughout the Measure Lifecycle, and uses it to compare actual results during measure reevaluation and maintenance. The business case should demonstrate

- why the measure is necessary
- the measure's value and how it balances benefits, costs, and risks, including burden
- viability of the measure relative to the health care sector's ability to respond
- whether the measure is sensitive to changes in behavior or policy such that improvements in measure performance reflect improvements in care delivery
- whether the costs of implementation are realistic
- whether the health care system has sufficient capacity to implement the measure.

Key elements of the business case include

- net benefit summary
- precise statement of need
- measure impact
- influencing factors
- resources required for measure implementation
- costs of clinical care.

Table 1 outlines several research questions measure developers should ask when developing a business case and key areas for which the measure could provide benefits and decrease or increase costs.

Table 1. Research questions to pose during business case development.

PRIMARY RESEARCH QUESTIONS
How will this measure improve health care quality, processes of care delivery, outcomes of care, and/or decrease complications or untoward effects of care?
How will the measure decrease variations to ensure best care for all?
How will implementing this measure decrease the cost of care ⓘ or improve clinical efficiency?
How does data collection for this measure affect clinical workflows?
What are the far-reaching, long-term benefits of this measure? Does it address a gap in care not addressed in the literature?
SECONDARY RESEARCH QUESTIONS
Does the measure promote coordinated care across settings?
Does the measure include the patient as a member of the care team?
AREAS OF POTENTIAL COSTS, BENEFITS, AND SAVINGS
• **Patients**: health outcomes, length of stay, readmissions, patient satisfaction, adverse events, medical errors, trust of the health care system. • **Employee and organizational**: workplace safety, staff time, staff turnover, sick time, training time, turnover hiring costs, staff supervision costs. • **Liability**: workers' compensation claims, liability insurance premiums, litigation and judgment costs, fines. • **Materials**: Product purchase, new technology or protocol, maintenance, storage, and disposal.

The cost savings analysis model is the method most commonly used to evaluate the business case. Regardless of the evaluation model, the business case should include a hypothesis that, at a minimum, states the measure's effect over time. These details enable the measure developer to make cost-benefit determinations during measure use, continuing evaluation, and maintenance.

REFERENCES	
MMS Hub	• Measure Conceptualization
SUPPLEMENTAL MATERIALS	• *Environmental Scans for Quality Measurement*
TEMPLATES	• Information Gathering Report Template • Business Case Form and Instructions

Measure Specification

This stage of the Measure Lifecycle consists of developing the technical aspects of the measure specifications and harmonization with related measures. Measure developers revisit the measure specification process throughout the Measure Lifecycle to incorporate shifting measure concepts and specifications based on testing results and changes to standards.

INTERESTED PARTY ENGAGEMENT

In addition to the technical expert panel (TEP), the measure developer should engage interested parties such as patients, caregivers, and clinicians at this stage to address the feasibility of data collection. The measure developer should also consider soliciting public comments on the *MMS Hub*. Measure developers may also post draft specifications for electronic clinical quality measures (eCQMs) to the ONC Project Tracking System.

MEASURE SPECIFICATIONS

DESCRIPTION Measure specifications are essentially the measure details; they include all the information required to define and calculate the measure. Development of specifications is an iterative process with testing.

PURPOSE Ensures measure details are clear and unambiguous, creating a unique measure distinguishable from others and to support consistent implementation.

MEASURE SPECIFICATIONS CHECKLIST

- ☐ Define the data source
- ☐ Develop specifications and definitions
- ☐ Specify the codes and code systems
- ☐ Construct the data protocol
- ☐ Document the measures

DEFINE THE DATA SOURCE(S): When identifying the source(s) of data, the measure developer must consider the feasibility and method(s) of collecting data from that source. Types of sources include administrative data, claims data, paper patient medical records, electronic patient medical records, electronic clinical data, registries, and standardized patient assessments. Each source has its own benefits and limitations, such as time commitments and staff resources. It is possible to use multiple sources, e.g., hybrid measures.

DEVELOP SPECIFICATIONS AND DEFINITIONS: The construction of measure specifications begins with the outline of the target/initial population, numerator, denominator, numerator and denominator exclusions, denominator exceptions, and measure logic. Then, the measure

developer gives the measure concept increasing amounts of detail, including precisely defined data elements ⓘ and the appropriate values, value sets ⓘ, or direct reference codes ⓘ. Every part of measure specification requires explicitly defined elements with accompanying analysis to identify constraints and criteria of the specification.

Table 2. Measure specification examples.

COMPONENT	DESCRIPTION	EXAMPLE
Target/Initial Population	Refers to the cohort for selecting the denominator population. Some measures (e.g., ratio ⓘ measures) will require multiple target/initial populations, one for the numerator and one for the denominator.	All patients aged 6 through 17 years with a diagnosis of major depressive disorder (MDD) (CMIT Measure ID 122).
Denominator	Describes the population evaluated by the individual measure. The population defined by the denominator can be the same as the target/initial population or it can be a subset of the target/initial population to further constrain the population for the measure. Format: patients, age [age or age range], with [condition] in [setting] during [time frame]	All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD [hemodialysis]) for the complete reporting month at the same facility (CMIT Measure ID 313) (CMS CBE 2978).
Denominator Exclusion	Denominator exclusions refer to criteria that result in removal of patients or cases from the denominator before calculating the numerator. An exclusion means the numerator event is not applicable to those covered by the exclusion. Format: denominator-eligible patients who [have some additional characteristic, condition, procedure]	Documentation stating the patient has had a diagnosis of bipolar disorder (CMIT Measure ID 672).
Numerator	Describes the process, condition, event, or outcome that satisfies the measure focus or intent. Format: patients who received/had [measure focus] {during [time frame] if different than for target population}	The number of adult patient-months in the denominator who were on maintenance hemodialysis using a catheter continuously for three months or longer as of the last hemodialysis session of the reporting month (CMIT Measure ID 313) (CMS CBE 2978).

COMPONENT	DESCRIPTION	EXAMPLE
Denominator Exception	An exception permits the exercise of clinical judgment and implies the measured entity considered or offered treatment to each potentially eligible patient in the denominator. Exceptions are most appropriate when measurements of contraindications to drugs or procedures are relative. Only use a denominator exception in proportion ⓘ measures. It is not appropriate for ratio or continuous variable ⓘ measures.	Documentation of medical reason(s) for not prescribing beta-blocker therapy (e.g., arrhythmia, bradycardia, patients with an atrioventricular block without cardiac pacer, observation of consecutive heart rates <50, low blood pressure, asthma, allergy, intolerance, other medical reasons). Documentation of patient reason(s) for not prescribing beta-blocker therapy (e.g., patient declined, other patient reasons). (CMIT Measure ID 306) (CMS CBE 0083e).
Numerator Exclusion	Used only in ratio and proportion measures to define elements that should not be in the numerator data.	If the number of central line bloodstream infections per 1,000 catheter days were to exclude infections with a specific bacterium, that bacterium would be listed as a numerator exclusion.
Stratification Scheme	Measure developers may define a stratification ⓘ scheme in lieu of risk adjustment ⓘ by stratifying the population based on their risk for an outcome of a procedure.	Measure is to be stratified by age group, i.e. patient age 16-20 and 21-64 by the end of the measurement period (e.g., Chlamydia Screening for Women [CMIT Measure ID 128]).

SPECIFY THE CODE AND/OR CODE SYSTEMS: Most measures rely at least in part on the use of various standardized codes or code systems for classifying health care provided in the United States. The measure developer should list all codes (plus the code system and the version the codes came from) required for the measure and explicitly state the source of the codes and instructions pertaining to their use. Find more information in Specify the Code section of the *MMS Hub*.

CONSTRUCT DATA PROTOCOL: The measure developer must explicitly identify the types of data and how to aggregate or link these data so the measure calculation can be reliable and valid. The measure developer should proceed carefully when merging data from different sources or systems to prevent errors in assumptions.

DATA PROTOCOL CHECKLIST
☐ Define key terms, data elements, codes, code systems
☐ Describe the level of measurement/analysis
☐ Describe sampling
☐ Determine risk adjustment, if appropriate

DATA PROTOCOL CHECKLIST
☐ Clearly define time intervals ⓘ
☐ Describe how the measure results are scored and reported
☐ Develop the calculation algorithm ⓘ

RISK ADJUSTMENT

Some measures, specifically outcome and cost measures ⓘ, may require risk adjustment. The purpose is a fairer and more accurate comparison of outcomes or cost of care across measured entities. Find more information about risk adjustment modeling in the *Risk Adjustment in Quality Measurement* content.

DOCUMENT THE MEASURE: The measure developer must complete the detailed technical specifications, including any additional documents required to evaluate and implement the measure as intended. The Measure Information and Justification Form, and information on the CMS CBE Endorsement and Maintenance webpage are available to assist in documentation of specifications.

HARMONIZATION	
DESCRIPTION	Harmonization is the standardization of specifications for related measures. Measure harmonization may be based on shared focus, target population, or definitions applicable to many measures so that they are uniform or compatible (unless there is a compelling reason not to, i.e., dictated by the evidence).
PURPOSE	Harmonization helps to reduce the burden associated with measure implementation and reporting at health care organizations. Harmonization efforts during development and maintenance help fulfill the CMS CBE requirement to provide evidence of a search for competing or related measures and a plan for harmonization or justification for identified measures. Find more information in the Measure Harmonization section on the *MMS Hub*.

Table 3 provides information about different scenarios for harmonization during measure development.

Table 3. Harmonization during measure development. N represents numerator and D represents denominator in the table.

MEASURE		HARMONIZATION ISSUE	ACTION
N	Same measure focus	Competing measure	• Use existing measure (adopted) ⓘ or justify development of a new measure • A different data source will require new harmonized specifications (e.g., respecified ⓘ)
D	Same target population		

MEASURE		HARMONIZATION ISSUE	ACTION
N	Same measure focus	Related measure	• Harmonize on measure focus (i.e., respecified) • Justify differences • Respecify existing measure by expanding the target population
D	Different target populations		
N	Different measure focus	Related measure	• Harmonize on target population • Justify differences
D	Same target population		
N	Different measure focus	New measure	• Proceed with new measure development
D	Different target population		

REFERENCES	
MMS Hub	• Measure Specification • Measure Harmonization
SUPPLEMENTAL MATERIALS	• *Composite Measures for Accountability Programs* • *Cost and Resource Use Measures* • *Electronic Clinical Quality Measures (eCQM) Specifications, Standards, and Tools* • *Multiple Chronic Condition Measures* • *Patient-Reported Outcome Measures* • *Risk Adjustment in Quality Measurement*

Measure Testing

Key components of measure testing include developing a testing plan, alpha and beta testing, and measure evaluation.

DESCRIPTION Testing refers to all the data collection and analysis activities contributing to the evaluation of the measure specifications.

PURPOSE Enables measure developers to assess the suitability of the technical specifications and acquire empirical evidence ⓘ to help assess the strengths and challenges of a measure with respect to the evaluation criteria, especially scientific acceptability (reliability and validity) and feasibility. Testing also provides an opportunity to build upon earlier judgments about the measure's importance and usability.

STEPS TO PERFORM TESTING

- ☐ Develop a plan for how to test the measure (ensure planned methods will address evaluation criteria)
- ☐ Implement the testing plan
- ☐ Analyze the test results
- ☐ Refine the measure; incorporate interested party inputs
- ☐ Retest the refined measure
- ☐ Document adherence to measure evaluation criteria:
  - ☐ Prepare for CMS CBE endorsement process (if applicable)
  - ☐ Compile information to support measure selection (see "Measure Implementation")

ALPHA AND BETA TESTING

Table 4 provides the features of both alpha and beta testing; measure developers should consider both when developing a testing plan.

Table 4. Features of alpha and beta testing.

	ALPHA TESTING	BETA TESTING
Timing	• Conducted prior to finalization of technical specifications • Can conduct multiple times in quick succession	• Conducted after development of the measure developer's detailed and precise technical specifications

	ALPHA TESTING	BETA TESTING
Scale	• Requires only enough records to ensure the presence of all elements needed for the measure and identify common occurrences or variation in the data	• Samples should be representative and of adequate size • May require data from multiple sites/settings, depending on the data source (e.g., administrative, patient medical record)
Sampling	• Convenience sampling	• Sufficient to allow adequate testing of the measure's scientific acceptability
Specification Refinement	• Permits early detection of problems in technical specifications (e.g., identification of additional inclusion and exclusion criteria)	• Used to assess or revise the complexity of computations required to calculate the measure
Importance	• May help assess volume, frequency, or costs related to a measure topic (e.g., cost of treating the condition, costs related to procedures measured) • Establishes, on a preliminary basis, the measure can identify gaps in care • Provides support for further development of the measure	• Includes empirical evaluation of performance thresholds, disparities ⓘ analysis, and outcome variation • Evaluates opportunities for improvement ⓘ in the population (e.g., by identifying variability among comparison groups, showing that the measure is not "topped-out ⓘ")
Scientific Acceptability	• Limited in scope if conducted during the formative stage • May include preliminary assessment of face validity	• Empirically assesses measure reliability and validity, including analysis of exclusion criteria (if any used) • Evaluates the risk adjustment model
Feasibility	• Provides initial information about the feasibility of collecting required data and calculating measures using technical specifications • Identifies barriers to implementation • Offers an initial estimate of costs or burden of data collection and analysis	• Provides enhanced information regarding feasibility, including greater determination of barriers and measured entity burden to implementation and costs associated with measurement • Evaluates feasibility of stratification factors based on occurrences of target events in the sample

	ALPHA TESTING	BETA TESTING
Usability and Use	• No formal analytic testing at this stage; may use qualitative testing with patients and measured entities during alpha testing • TEP may assess potential usability of the measure	• Identifies unintended consequences, including susceptibility to inaccuracies and errors • Reports strategies to ameliorate unintended consequences • May consist of focus groups or similar means of assessing usefulness of the measure by interested parties • Can use the TEP to assess potential usability

DEVELOP THE TESTING PLAN: A testing plan (also referred to as a work plan for testing) should include enough information to explain how the proposed testing methodology will help meet the evaluation criteria. Testing plans for alpha testing may look a bit different than testing plans for beta testing; at a minimum, however, all testing plans should contain the elements listed. See the Develop the Testing Work Plan section of the *MMS Hub* for more information.

TESTING PLAN ELEMENTS
☐ Name(s) of measure(s)
☐ Type of testing
☐ Study objective(s)
☐ Timeline for testing and report completion
☐ Data collection methodology
☐ Description of test population (e.g., number of test sites/data sets)
☐ Description of data elements to be collected
☐ Sampling methods, if applicable
☐ Description of strategy to recruit measured entities/test data sets
☐ Planned analysis methods and description of test statistics
☐ Description and forms documenting patient confidentiality and description of Institutional Review Board (IRB) compliance approval and/or steps to obtain data use agreements, if necessary
☐ Methods to comply with the Paperwork Reduction Act (PRA), if relevant

ANALYZE THE TEST RESULTS: When the measure developer completes data gathering from the test sites, the measure developer conducts a series of analyses to characterize the evaluation criteria of the measures. The measure developer presents findings of testing analyses in a final summary report.

REFINE THE MEASURE: The measure developer may need to modify the measure specifications, data collection instructions, and calculation of measure results based on analysis of testing results. For example,

- Following alpha testing, the measure developer may undertake measure respecification or efforts to overcome potential implementation barriers.
- Following beta testing, changes in the definition of the population or adjustments to the comparison group definition may occur.

INTERESTED PARTY ENGAGEMENT OPPORTUNITY

If making changes to the measure, consult with the TEP prior to retesting the measure. View Figure 3. *Interested party engagement and development activities accomplished during the Measure Lifecycle***.** graphic for more information.

RETEST THE MEASURE: Measure testing is an iterative process. Continue to refine and retest the measure as deemed necessary.

EVALUATE THE MEASURE: Throughout the Measure Lifecycle, especially through testing, the measure developer evaluates the measure to determine the degree to which it is consistent with the evaluation criteria. The measure developer uses resulting evaluation information to determine how to modify the measure to increase the importance, scientific acceptability, usability and use, and feasibility.

REFERENCES	
MMS Hub	• Measure Testing
SUPPLEMENTAL MATERIALS	• *Composite Measures for Accountability Programs* • *Cost and Resource Use Measures* • *Electronic Clinical Quality Measures (eCQM) Specifications, Standards, and Tools* • *Patient-Reported Outcome Measures*
TEMPLATES	• Measure Evaluation Report Template

Measure Implementation

This stage of the Measure Lifecycle includes all activities associated with taking a measure from a development state to an active, in-use state, which includes−but not limited to−consensus endorsement processes, measure selection processes, and measure rollout.

DESCRIPTION

The implementation process measures undergo varies significantly on several factors, which may include

- scope of measure implementation
- measured entity being measured
- data collection processes
- ultimate use of the measure (e.g., quality improvement, public reporting, pay-for-reporting, or value-based purchasing)
- program into which the measure is added.

The scope of implementation could entail a measure or measure set ⓘ

- implemented in a new program
- added to an existing program.

PURPOSE

Implementation processes ensure careful review of all new and respecified measures to ensure the selection of only high-quality, meaningful measures meeting the needs of CMS programs.

CMS CBE ENDORSEMENT: To the extent feasible, CMS uses CMS CBE-endorsed measures in CMS public reporting and value-based purchasing programs. Measure developers must consider several items to facilitate the CMS CBE submission process as well as minimize rework.

CONSIDERATIONS TO FACILITATE CMS CBE SUBMISSION
☐ Provide clear, concise, and substantive answers to all sections of the CMS CBE submission form.
☐ Ensure reviewers can understand the CMS CBE submission form as a standalone document; all attachments, uniform resource locators (URLs), and references must include specific page numbers or table number references.
☐ Provide the code list, risk adjustment methodology, and calculation algorithm as attachments or URLs.
☐ For eCQMs, include the Measure Authoring Development Integrated Environment (MADiE)-exported human-readable hypertext markup language (HTML) and executable files and URLs to value sets and direct reference codes in the attachments.
☐ Include testing information, as applicable.
☐ Give clear rationales for decisions related to measure specifications, including use of numerator and denominator exclusions and denominator exceptions.

CONSIDERATIONS TO FACILITATE CMS CBE SUBMISSION

- ☐ Provide explanations of controversies about the science behind the measure.
- ☐ Confirm points of contact on the Intent to Submit and Full Measure Submission forms are accurate.

MEASURE SELECTION

CMS measure selection criteria help to ensure each measure

- supports the CMS and national health care priorities, prioritizing outcome measures, patient-reported outcome measures, digital measures, and best care for all
- is responsive to specific program goals and statutory requirements
- addresses an important condition topic with a performance gap and strong scientific evidence base to demonstrate the measure can lead to the desired outcomes and/or more affordable care
- has written consent for any proprietary algorithms needed for measure production
- promotes alignment with CMS program attributes and across Department of Health and Human Services (HHS) programs
- identifies opportunities for improvement. (e.g., not topped out)
- does not result in negative unintended consequences (e.g., overuse or inappropriate use of care or treatment, limiting access to care)
- does not duplicate another measure currently implemented in one or more programs.

If it is an eCQM, the measure developer must create using the MADiE and express in Health Quality Measure Format (HQMF)ⓘ using the Quality Data Model (QDM)ⓘ and Clinical Quality Languageⓘ.

MEASURE SELECTION PROCESSES

DESCRIPTION

Different CMS programs have different paths a measure can take for selection and implementation. In general, measures undergo identification and finalization during a rigorous process involving public input.

PROCESS

For measures subject to the pre-rulemaking and rulemaking process, the next section, Pre-Rulemaking & Rulemaking, discusses that process.

For measures not subject to pre-rulemaking or rulemaking

- the measure selection process may include CMS issuing a call for measures to solicit measures and/or identify measures considered for removal
- have these measures available for comment by the public and/or a TEP.

PRE-RULEMAKING & RULEMAKING

DESCRIPTION Pre-rulemaking and rulemaking represent one specific pathway for measure selection. The programs participating in the CMS pre-rulemaking and rulemaking process include those identified under the Patient Protection and Affordable Care Act (ACA) Section 3014. Measure developers submit measures for potential inclusion in the Measures Under Consideration (MUC) List for these programs. The MUC List, which CMS publicly posts, is a list of the measures HHS is considering adopting through the federal rulemaking process for use in several Medicare quality and payment programs.

PURPOSE Maximize transparency and rigor in the measure identification and selection process.

In Figure 2, the gray boxes provide an overview of the pre-rulemaking process through the publication of the MUC List. The bottom of the figure describes measure developer activities occurring at various points in the pre-rulemaking process.

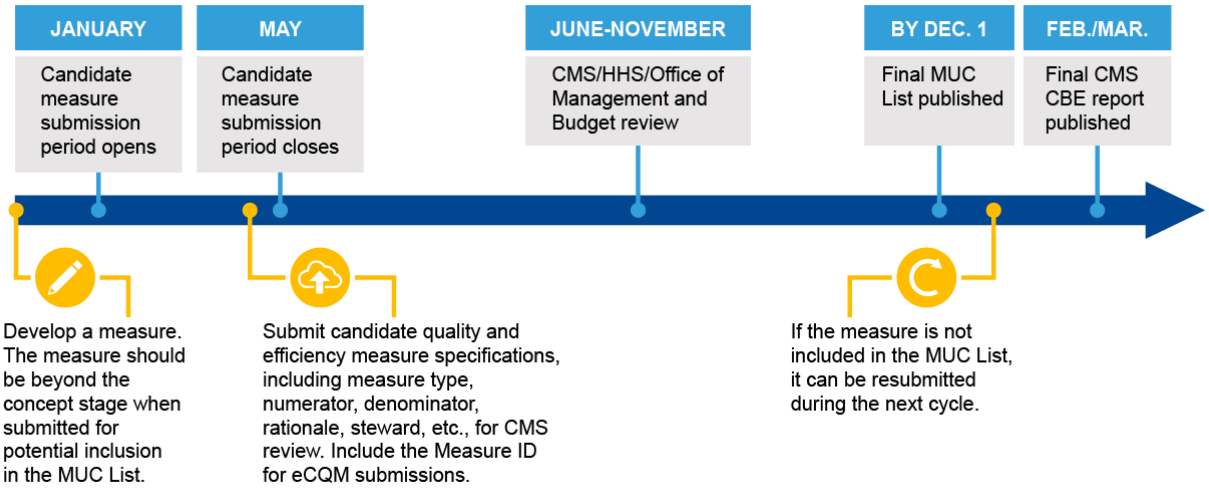

Figure 2. Pre-rulemaking timeline.

CMS provides the finalized MUC List to the CMS CBE. The CMS CBE convenes interested parties to provide recommendations on the MUC List. The CMS CBE and CMS publish the final recommendations by February 1. CMS encourages measure developers to attend the MUC List review meeting(s) to be fully involved in the process. After CMS receives the input and recommendations, CMS begins a deliberation process to determine which measures to include in the federal rulemaking process. The measure selection criteria used during development of the MUC List are the same criteria used for federal rulemaking. HHS must consider the interested parties' input and publish—in proposed or final rules--the rationale for selecting any measure for use in a CMS program that is not recommended by the interested parties. A rationale must also be provided for selecting any measure for use in a CMS program (except MIPS) that is not endorsed by the CMS CBE.

RULEMAKING

After CMS completes the pre-rulemaking process and selects measures for potential inclusion in rulemaking, the next steps in the cycle are

1. **PROPOSED RULES:** CMS develops the proposed rules and publishes them in the Federal Register. A proposed rule is generally available for public comment for 60 days.
2. **FINAL RULES:** CMS considers the comments received and publishes the final rules in the Federal Register.

MEASURE ROLLOUT

Measure rollout always occurs after a program adopts the measure and every measure has a rollout regardless of the adoption process. The rollout process may include collection of data for a dry run ⓘ from all relevant measured entities across the country and sharing of calculated rates with the measured entities. CMS does not use dry run data for payment but may use them as a baseline for future payment years.

When communicating and coordinating with all parties involved in the rollout, the measure developer must consider the timelines of other processes (for example, rulemaking, CMS CBE projects, and quality alliances). The measure developer prepares and presents education for the end users on what is being measured and how to interpret the results.

The measure developer also documents the results of any educational activities and assesses whether the activities were adequate to meet the needs of the end users of the measures. For example, the measure developer should report on the number of events, including the attendance at each

- conference call and call recording
- web-based presentation and presentation recording
- workshop at conference or scientific society meeting
- train-the-trainer event.

MEASURE STEWARDSHIP

A measure steward ⓘ is the individual or organization that owns a measure and is responsible for maintaining it. Sometimes the measure steward is also the measure developer. If an existing measure in a program undergoes a substantive change during any of these updates, it is the responsibility of the measure steward to resubmit the measure to restart the measure selection process.

REFERENCES	
MMS Hub	• Measure Implementation • CMS Consensus-Based Entity (CBE) Endorsement and Maintenance

Measure Use, Continuing Evaluation, and Maintenance

To help CMS ensure the continued soundness of a measure, the measure developer must provide strong evidence a measure currently in use continues to add value to quality reporting and incentive programs and that its construction continues to be sound throughout its lifecycle.

DESCRIPTION The processes for continuous review and evaluation for appropriateness of measures currently used in programs.

PURPOSE Maintenance and continuing evaluation ensure the measure continues to meet criteria of importance, feasibility, scientific acceptability, and usability and use.

CONTINUING EVALUATION

DESCRIPTION Continuing evaluation refers to the process through which the measure developer updates measure specifications to demonstrate the measure's continued suitability for use.

MAINTENANCE

DESCRIPTION Measure maintenance is a multi-step review process that includes annual updates, comprehensive reevaluations, and early maintenance reviews.

STEPS FOR CONTINUING EVALUATION AND MAINTAINING A MEASURE

- ☐ Conduct data collection and ongoing surveillance
- ☐ Respond to questions about the measure
- ☐ Produce preliminary reports
- ☐ Report measure results
- ☐ Monitor and analyze measure rates and audit findings
- ☐ Perform measure maintenance or early maintenance review, when appropriate
- ☐ Provide information CMS can use in measure priorities planning

REFERENCES	
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Interested Party Engagement

Measure developers and other groups seek advice requesting input from a diverse group of interested parties when undertaking quality measurement projects, especially when developing quality measures. This engagement helps them balance a variety of perspectives and interests and leads to better clinical outcomes. As a result, interested party engagement is a critically important task to support CMS's aims to gather information about future measurement needs and to conduct its measurement activities transparently.

DESCRIPTION Interested party engagement involves gathering information from a wide variety of individuals—such as clinicians, patients, caregivers, advocates and advocacy groups, and specialty societies—through TEPs, person and family engagement opportunities, public comment, and other interested party outreach.

PURPOSE Promotes transparency in the measure development process. Yields information demonstrating the measure's importance, usability, feasibility, and face validity ⓘ.

TEP

- *Description*: a group of experts and interested parties, including patients, families, caregivers, and others, who provide feedback to the measure developer during every stage of the Measure Lifecycle, from conceptualization through maintenance.
- *Purpose*: obtain guidance and thoughtful input from varied perspectives on what is important to measure and evaluate for a balanced quality measure useful to interested parties.

Person & Family Engagement (PFE)

- *Description*: the process of meaningfully involving persons and/or family representatives throughout the Measure Lifecycle. Forms of involvement include informal conversations, focus groups, or TEPs. CMS uses the term "person" to reflect an individual's identity as more than a patient while "family" broadly represents any participant in a person's health care, such as caregivers, advocates, and advocacy groups. As a best practice, include at least two persons and/or family members on a TEP. Visit the CMS *Person & Family Engagement Strategy* and the *Person and Family Engagement Toolkit* for more information.
- *Purpose*: identify issues important and meaningful to persons and families, helping measure developers create high-quality measures that enable consumers to make informed health care decisions.

Public Comment

- *Description*: an opportunity for the widest array of interested parties to provide input on the measure.
- *Purpose*: solicit critical suggestions not previously considered by the measure developer or TEP, ensuring balance and transparency in measure development and maintenance.

Engagement of Other Interested Parties

- *Description:* targeted outreach to interested parties and subject matter experts to provide input on the measure.
- *Purpose:* solicit suggestions, potentially to answer specific questions, outside of the more formal processes of TEPs and public comment, for example focus groups and expert interviews.

Interested party activities occur throughout the Measure Lifecyle. Figure 3 provides examples of Interested party engagement actions and goals during different stages of the Measure Lifecycle.

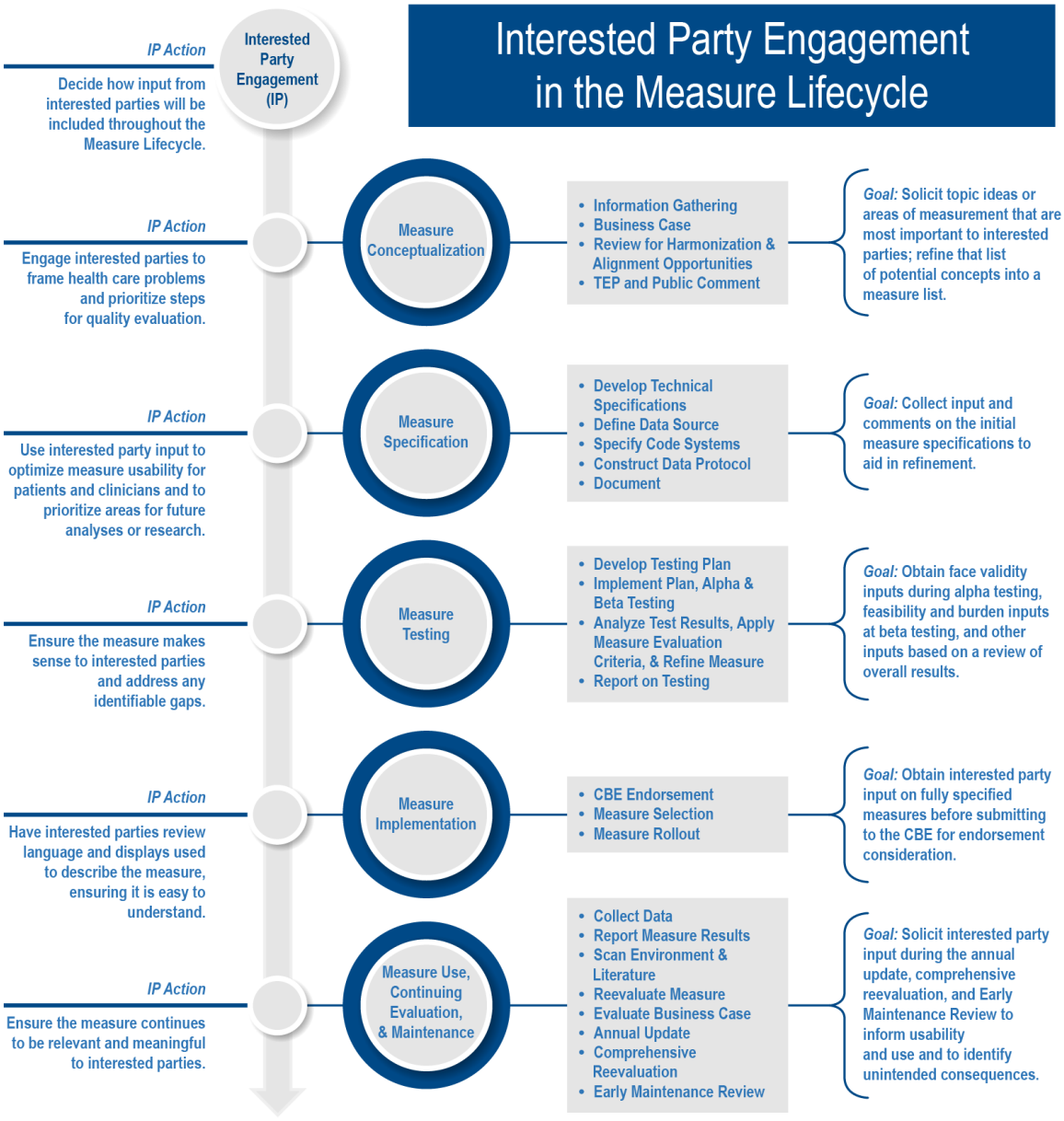

Figure 3. Interested party engagement and development activities accomplished during the Measure Lifecycle.

REFERENCES	
MMS Hub	• Interested Party Engagement
SUPPLEMENTAL MATERIALS	• *Person and Family Engagement in Quality Measurement* • *Technical Expert Panels (TEPs)*

Conclusion

The quality and efficiency measures ⓘ developed for use in CMS programs have a real-world effect on patients, families, and measured entities. Implementation and use of thoughtfully developed measures has positively influenced several critically important metrics at the national level.

For more in-depth information about the Measure Lifecycle, access the Measure Lifecycle content on the *MMS Hub*, supplemental materials, and templates, which provide greater context and additional detail on the topics highlighted in this guide. Visit the *MMS Hub* for educational presentations.

Contact the MMS Support Team at MMSsupport@battelle.org if you have additional questions.