Measure Maintenance Reviews of Quality Measures

The purpose and extent of a measure maintenance review varies depending on the type of review. This document describes three types of maintenance reviews, including the steps required for each:

- annual update
- comprehensive reevaluation
- early maintenance review

The information in this document supplements the information found in the Blueprint content on the MMS Hub, Measure Maintenance. For more information about CMS consensus-based entity (CBE) endorsement, see the CMS Consensus-Based Entity (CBE) Endorsement and Maintenance supplemental material.

1 Annual Update

One type of quality measure reevaluation is the annual update, which is usually a limited review of the precision of the measure’s specifications—completed annually (or semiannually, in some cases). Annual updates ensure updates to the quality measure’s procedure, diagnostic, and other codes (e.g., Current Procedural Terminology [CPT], International Classification of Diseases, 10th Revision, Clinical Modification/Procedure Coding System [ICD-10-CM/PCS], Logical Observation Identifiers Names and Codes [LOINC]) when code systems change. However, if implemented, this is also the time to review and address feedback received from stakeholders about the measure’s specifications. Measure...
developers should always review the measure for reliability, and validity, and for harmonization opportunities. For more information on codes see the Codes, Code Systems, and Value Sets supplemental material.

The annual update process involves three parts, divided into six steps outlined in Section 1.1, Annual Update Procedure:

- gathering information generated since the last review (i.e., comprehensive reevaluation, annual update, or measure development—whichever occurred most recently)
- recommending action
- approving and implementing the action(s)

The measure developer should consider feedback from measured entities to address feasibility concerns for electronic clinical quality measures (eCQMs) and implement suggested code changes to address validity. For more information on the eCQM Annual Update see the Electronic Clinical Quality Measures (eCQMs) Specifications, Testing, Standards, Tools, and Community supplemental material.

For endorsed measures, during the 2 years when an endorsed measure is not being reevaluated for continued CMS CBE endorsement, measure stewards may submit the online, annual update form(s) to the CMS CBE for continued endorsement. This submission either reaffirms that the measure specifications remain the same as those at the time of endorsement or last update or outline any changes or updates made to the endorsed measure.

If a measure changes at any time during the 3-year endorsement period, the measure steward is responsible for informing the CMS CBE immediately of the timing and purpose of the changes. The CMS CBE may request an early maintenance review if the changes materially affect the measure’s result (e.g., changes to the target/initial population, changes in measurement, inclusion of new data sources, expansion of the level of analysis or care settings).

1.1 ANNUAL UPDATE PROCEDURE

To perform an annual update, the measure developer should perform seven steps as outlined in Sections 1.1.1-1.1.7:

1.1.1 Review the Measure’s Code Systems

The measure developer reviews the code systems used by the measure to determine whether

- addition or deletion of new codes from the code systems may affect the measure
- codes changed so that their new meaning affects their usefulness within the measure

If not specified with ICD-10-CM/PCS codes, the measure developer converts any ICD-9-CM codes in the measure to ICD-10-CM/PCS unless needed for a look-back period or historical data past October 1, 2015.

When maintaining eCQM value sets, it is important to align with the vocabulary recommendations made by the Office of the National Coordinator for Health Information Technology in the Interoperability Standards Advisory.

1.1.2 Gather Information

The expectation is the measure developer conducts environmental scans continually. This process includes reviewing and managing stakeholder comments on the quality measure, e.g., from public
comments on proposed rules, and reviewing literature pertinent to the measure. The CMS Environmental Scan Support Tool (ESST) and monthly measure scans can assist with the ongoing environmental scans. The measure developer should consider all new information during the annual update, with special consideration given to evidence of unforeseen adverse consequences or measure-related controversies. This surveillance may result in an early maintenance review by the CMS CBE.

If there is a resolution to stakeholder feedback requiring minimal change to the measure, the measure developer should consider doing so. If the feedback indicates a serious scientific concern with the clinical practice underlying the measure, the measure developer should consider performing an early maintenance review. A discussion of the details of the early maintenance procedure is in Section 3, Early Maintenance Review. The measure developer should evaluate the feasibility and impact of changing measure specifications. If feedback during the review recommends modifications, the measure developer should conduct a limited review of measure performance including

- national performance rates
- state and regional performance rates
- variations in performance rates
- validity of the measure and its constituent data elements
- reliability of the measure and its constituent data elements

### 1.1.3 Determine the Recommended Disposition of the Measure

A discussion of the criteria that form the basis for the disposition decision for each measure and description of the possible outcomes is available in the Blueprint content on the MMS Hub, Measure Maintenance Reviews.

The possible dispositions used by most CMS programs are

- Retain - keep the measure active with its current specifications and minor changes.
- Revise - update the measure’s current specifications to reflect new information.
- Remove - eliminate a measure in a specific program set for one or more reasons. This does not imply that other payors/purchasers/programs should cease using the measure. If CMS is the measure steward and another CMS program continues to use the measure, CMS may continue to maintain the measure. If another entity is the steward, the other payors/purchasers/programs that may be using the measure are responsible for determining if the steward should continue to maintain the measure.
- Retire - cease to collect or report the measure indefinitely. This applies to measures unowned or maintained by any measure steward. If it is necessary to retire a measure from a set, other replacement measures may be available to complement the remaining measures in the set.
- Suspend - temporarily cease to report a measure. Data collection and submission may continue.

### 1.1.4 Implement the Disposition Action

For measures proposed for revision, suspension, removal, or retirement, the measure developer should evaluate the impact of the decision on the program using the measure when developing the implementation plan. If there are relevant regulatory or rulemaking schedules, the measure developer should include them in the implementation plan.
1.1.5 Consider Measures Not Stewarded by CMS

When CMS is not the measure steward (i.e., not ultimately responsible for maintaining the measure), the measure developer is responsible for monitoring the maintenance of the measure. This includes ensuring periodic revisions to the measure in response to updates in the underlying code systems (e.g., CPT, ICD-10-CM, LOINC) and that the measure is reevaluated in a manner consistent with (though not necessarily identical to) the reevaluation requirements discussed in Section 2, Comprehensive Reevaluation.

1.1.6 Notify the CMS CBE of the Updated Measure

After the CMS CBE endorses a measure, the measure steward may request to submit a status report of the measure specifications to the CMS CBE annually. This report either affirms that the detailed measure specifications of the endorsed measure have not changed or, if the measure developer is making changes, it provides details and underlying reasons for the change(s). If the measure developer makes changes to a measure at any time in the 3-year endorsement period, the measure steward must inform the CMS CBE immediately of the timing and purpose of the changes.

The CMS CBE provides a standardized template for submission of an annual measure maintenance update prepopulated with measure information. The measure developer is responsible for preparing this report for the CMS CBE. If the changes materially affect the measure’s original intent, the CMS CBE may conduct its own early maintenance review. The measure developer responsible for measure maintenance should be aware of the CMS CBE’s measure maintenance schedule and when the annual update is due to the CMS CBE. The measure developer should confirm annually the due date for their measure update with CMS CBE because schedules may change. The measure developer should also inform the CMS CBE of any contact information changes so the correct recipients receive the notifications.

1.1.7 Submit the CMS CBE Annual Status Update Report

The measure developer prepares the annual update report of the measure specifications, and submits it online to the CMS CBE, if the measure steward requests submission. Some measures in the maintenance phase may require updates more than once per year. In those cases, the measure developer should notify the CMS CBE of the changes as often as appropriate.

The CMS CBE reviews submitted annual updates on a quarterly basis.

2 COMPREHENSIVE REEVALUATION

Measure developers should conduct, and the CMS CBE requires, a thorough review of the measure every 3 years. In many ways, the comprehensive reevaluation process parallels the measure development process.

A comprehensive reevaluation consists of information gathering (including a literature review of recent studies and clinical practice guidelines), analysis of measure performance rates, and synthesis of all feedback received. Measure developers usually convene and consult a Technical Expert Panel (TEP) as part of the comprehensive review.

The comprehensive reevaluation process includes nine steps, outlined in Section 2.2, Comprehensive Evaluation Procedure, which falls into three phases:
• gathering information generated since the measure’s development or since the last comprehensive reevaluation, whichever occurred most recently
• evaluating the measure and recommending action based on the evaluation
• approving and implementing the action

The comprehensive reevaluation process assumes the measure developer has been monitoring the scientific literature and clinical environment related to the measure, including relevant clinical guidelines.

2.1 Harmonization During Comprehensive Reevaluation

Whenever a measure developer reevaluates a measure, the measure developer must compare the measure to related or competing measures, assessing for the possibility of harmonization. If the measure developer identifies related measures, they should consider ways they can align the measure being reevaluated with the related measures. If the measure developer identifies competing measures, they should either justify why the reevaluated measure is best in class or give a rationale for continuing with possibly duplicative measures.

If measure specifications need alterations so they can harmonize with other measures, the changes could be substantive. The comprehensive reevaluation period may be the best time to make these changes. During its maintenance reviews, the CMS CBE will evaluate measures for harmonization opportunities. For more information about harmonization, see the Quality Measure Harmonization, Respecification, and Adoption supplemental material.

2.2 Comprehensive Reevaluation Procedure

2.2.1 Develop a Work Plan

The measure developer begins the comprehensive reevaluation process by developing a work plan. When developing the work plan, the measure developer should consider two other schedules:

• rulemaking cycle for any regulatory process governing the measure set in question
• the CMS CBE’s measure maintenance schedule, if applicable

2.2.2 Gather Information

The measure developer should conduct ongoing surveillance during measure monitoring and summarize the findings of their environmental scan in a report, e.g., ESST monthly reports. The ongoing environmental scan should focus on information published or otherwise available since the last measure evaluation.

At a minimum, this synthesis should include

• changes to clinical guidelines on which the measure is based, e.g., monitor ECRI Guidelines Trust
• relevant studies that might change clinical practice, which in turn, might affect the underlying assumptions of the measure
• relevant studies that document unintended consequences of the measure
• relevant studies that document continued variation or gaps in the measured care
• technological changes that might affect the collection, calculation, or dissemination of data
similar measures based on their structure, clinical practices, or conditions that could offer an opportunity for harmonization or might serve as replacement measures
• relevant information gathered from the TEP or interviews with subject matter experts or measurement experts
• patients’ perspective on the measure
• reevaluation of the business case supporting the measure
• feedback received since the last measure evaluation (i.e., the initial evaluation or the last comprehensive reevaluation, whichever is most recent)

The measure developer should obtain measure performance information including, but not limited to

• current aggregate national and regional measurement results
• measurement results trended across the years since the measure’s initial implementation
• comparison to the trajectory predicted in the business case
• current distribution of measurement results by measured entity types (e.g., rural vs. urban, for-profit vs. nonprofit, facility bed size)
• analysis of the measure’s reliability, stability, and validity since implementation
• results of audit and data validation activities
• analysis of any disparities in quality of care based on race, ethnicity, age, social risk factors, income, region, gender, primary language, disability, or other classifications, including a determination the reduction of elimination of any disparities identified earlier
• analysis of unintended consequences that have arisen from the use of the measure
• validation and analysis of the numerator and denominator exclusions, including, but not limited to
  o analysis of variability of use
  o implications of rates

The measure developer compares the information gathered with projections made in the original business case and reports the measure performance and the impact of the measure. The measure developer should update the business case as appropriate and make projections for the next evaluation period.

2.2.3 Convene a TEP

Typically, the measure developer convenes a TEP during comprehensive reevaluation to assess the measure. It is a best practice for the measure developer to continue with the TEP that was involved with measure development. However, the measure developer should review the membership to ensure continued representation of an appropriate breadth of expertise and diversity. The Blueprint content on the MMS Hub, Stakeholder Engagement, and the Technical Expert Panel supplemental material provide details of the standardized process for issuing a call for nominations and convening a TEP.

During the TEP meeting, the measure developer presents the results of the environmental scan, literature review, and empirical data analysis of the measure performance data, patients’ perspective, and analysis of ongoing feedback received. If information about the patient perspective is not available, the measure developer will want to ensure that the TEP includes patient representative(s). Using input from the TEP, the measure developer develops recommendations on the disposition of the measure.

For CMS measures, the measure developer may request data via a Data Use Agreement. Similar data opportunities may be available from other organizations using quality measures.
using the measure evaluation and selection criteria. The Blueprint content on the MMS Hub, Testing and Measure Evaluation Criteria describes the measure evaluation criteria and there is a discussion of the measure selection criteria in the Blueprint content on the MMS Hub, Measure Selection.

2.2.4 Identify and Document Recommended Changes

For each measure, the measure developer compiles the information gathered in the steps outlined in Sections 2.2.1-2.2.3 using the measure evaluation criteria.

The measure developer should identify any material or substantive changes and explain the purpose of the changes. A material or substantive change is one that changes the specifications of a measure to affect the original measure’s concept or logic, the intended meaning of the measure, or the strength of the measure relative to the measure evaluation criteria.

2.2.5 Determine the Preliminary Recommended Disposition of the Measure

A discussion of the criteria that form the basis for the disposition decision for each measure and description of the possible outcomes is in the Blueprint content on the MMS Hub, Measure Maintenance.

The possible dispositions include (for definition, see Section 1.1.3, Determine the Recommended Disposition of the Measure)

- retain
- revise
- remove
- retire
- suspend

2.2.6 Test Measures as Necessary

For the first comprehensive reevaluation, the measure will require evaluation of reliability and validity beyond what occurred during measure testing at the time of development. If the measure is not in use, it will require expanded testing. Table 1 outlines the extent of measure testing or reevaluation of validity and reliability for measures in use and not in use.

Table 1. Extent of Measure Evaluation as a Function of Prior Comprehensive Evaluation and Measure Use

<table>
<thead>
<tr>
<th>Measure in Use</th>
<th>Measure Not in Use</th>
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<tbody>
<tr>
<td>First comprehensive reevaluation</td>
<td>Measure developer should obtain data from the population measured and analyze it to augment previous evaluation findings obtained from initial measure development and endorsement. If making material changes at this time, test the revised measure.</td>
</tr>
<tr>
<td>Subsequent comprehensive reevaluations</td>
<td>If measure has not materially changed, the CMS CBE may want minimal analysis and prior data for maintenance if past results demonstrated a high rating for reliability and validity of the measure.</td>
</tr>
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</table>
If the measure needs testing, the measure developer should develop a plan. A description of the components of a testing plan are in the Blueprint content on MMS Hub, Develop the Testing Work Plan.

### 2.2.7 Obtain Public Comment on the Measure

If there have been substantive changes to a measure as the result of comprehensive reevaluation, the measure developer should seek public comment on those changes. If the comprehensive reevaluation results in a recommendation to retain the measure with only minor changes, it likely is not necessary to seek public comment. Find the process for obtaining public comment in the Blueprint content on the MMS Hub, Stakeholder Engagement.

The measure developer next analyzes the comments received and refines the measure as indicated. Depending on the extent of measure revisions, the measure developer may deem it necessary to retest the measure.

### 2.2.8 Implement the Disposition Action

After review, the measure developer may be responsible for implementing the chosen measure disposition. When proposing measures for revision, suspension, removal, or retirement, the measure developer should evaluate the impact of the decision on the program using the measure when developing the implementation plan. If there are relevant regulatory or rulemaking schedules, the measure developer should include them in the implementation plan.

### 2.2.9 Maintain CMS CBE Endorsement

The CMS CBE requires comprehensive review every 3 years to maintain continued endorsement. Endorsed measures are reevaluated against the CMS CBE’s Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement and reviewed alongside newly submitted (but not yet endorsed) measures. This head-to-head comparison of new and previously endorsed measures fosters harmonization and helps ensure the CMS CBE is endorsing the best available measures. A description of the CMS CBE maintenance requirements, including the schedule, is on the CMS CBE website.

Ideally, the comprehensive reevaluation should precede the CMS CBE scheduled review so measure developers can determine the outcome of the reevaluation and address any identified harmonization issues. Measure developers will need to factor the time required for testing significant changes into the timing of the comprehensive reevaluation.

The notification of when a measure is due to expire will appear on the measure developer’s CMS CBE dashboard. The CMS CBE usually sends reminders and email notifications about the maintenance review due date; however, measure developers must be aware of the CMS CBE endorsement expiration dates and seek advice from the CMS CBE if they have not received notification of an endorsement maintenance review.

The CMS CBE will send a standardized online submission template for the 3-year endorsement maintenance review to the measure steward of record. The CMS CBE will prepopulate the form with information from the original or most recent annual update submission.

The 3-year maintenance review report documents the review of the current evidence and guidelines and provides information about how the measure still meets the criteria for the CMS CBE endorsement. The measure developer will use information from the most recent comprehensive reevaluation,
subsequent annual updates, and ongoing surveillance to complete the appropriate CMS CBE measure submission form.

3  **EARLY MAINTENANCE REVIEW**

An early maintenance review is a limited examination of the measure based on new information. If evidence comes to light before the annual or triennial review that may have a significant, adverse effect on the measure or its implementation, the measure developer should conduct an early maintenance review. The measure developer should complete early maintenance reviews as quickly as possible regardless of annual or 3-year scheduled comprehensive reviews because of the nature of the triggering information. The early maintenance review process ensures the measures remain balanced between the need for measure stability and the reality that the measure environment is constantly shifting. To preserve measure stability, the measure developer should reserve early maintenance review for instances when new evidence indicates the need for a very significant revision.

Early maintenance review specifically does not include the process of adapting or harmonizing a measure for use with a broader or otherwise different population.

3.1  **TRIGGER FOR AN EARLY MAINTENANCE REVIEW**

The early maintenance review process begins when the measure developer becomes aware of evidence – either through ongoing surveillance or other stakeholders – that may have a significant, adverse effect on the measure or its implementation. If it is a CMS CBE-endorsed measure, the CMS CBE may have received a request for an early maintenance review.

3.2  **DEFERRING AN EARLY MAINTENANCE REVIEW**

The measure developer should postpone an early maintenance review to the next scheduled review if that is reasonable. The presence of any accompanying patient safety concerns associated with the changes to the endorsed measure will influence the timing of the early maintenance review. If the measure developer will be updating or reevaluating the measure in the near future, they should incorporate the information received into that update or reevaluation. For example, if the measure is due for a comprehensive reevaluation or an annual update within the next 120 days, the measure developer should refer the information to the team conducting the review and that team should incorporate the early maintenance review process into its work.

3.3  **EARLY MAINTENANCE REVIEW PROCEDURE**

The early maintenance review process includes six steps, outlined in Sections 3.3.1-3.3.6, comprising three primary subparts:

- determining whether to conduct an early maintenance review
- conducting the review and recommending an outcome
- approving and implementing the approved outcome

3.3.1  **Determine Whether the Concern Is Significant**

If the clinical practice underlying the measure is causing harm to patients (directly or as a function of unintended consequences), the measure developer should revise, suspend, remove, or retire the measure. Although there is no defined schedule for this process, the CMS CBE may require the measure
developer to give the measure urgent attention. If measure revision is not feasible in the time frame necessary, the measure developer should suspend or retire the measure.

If there are no projections of patient harms, only the strongest concerns will result in an early maintenance review. The measure developer monitoring the measure should consider first whether the issue is significant and then may engage the TEP most recently involved with the measure. If the measure developer does not have access to the TEP, they may contact a professional association closely associated with the measure for input regarding the significance of the issue raised. The CMS CBE may also be the source of the request for urgent early maintenance review depending on the nature and source of the concerns.

If experts determine that the issue is not significant, the measure developer should document the issue for consideration at the next scheduled review.

3.3.2 Conduct Focused Information Gathering

The measure developer conducts a literature review to determine the extent of the issue(s) that triggered the early maintenance review and identify significant areas of controversy if they exist. Unlike environmental scans conducted during measure development, ongoing surveillance, or comprehensive reevaluation, the measure developer should limit the scan performed for an early maintenance review to new information directly related to the issue(s) that triggered the review. Investigation of all aspects of the measure is not necessary—only the aspect that generated concern.

Detailed guidance for conducting and documenting the environmental scan (including the literature review) is in the Blueprint content on the MMS Hub, Conduct an Environmental Scan and the Environmental Scans for Quality Measurement supplemental material.

3.3.3 Consult with the Experts, Especially the TEP

If feasible, the measure developer should consult with the TEP that contributed to the most recent comprehensive reevaluation or measure development.

If the issue generating the concern relates to clinical guidelines, the measure developer should ask the organization responsible for the guidelines about its plans for updating the guidelines or issuing interim guidelines. The measure developer may also consult professional organizations closely related to the measure.

The measure developer should ask the experts (e.g., TEP, guideline writers, professional organizations) about the

- significance of the issue, to confirm that they consider it important
- risk of possible patient harm if the measure remains in use, including harm from unintended consequences
- feasibility of implementing measure revisions, including cost and time

3.3.4 Determine Whether It Is Feasible to Change the Measure

Assessing the feasibility of changing a measure should include consideration of the cost of resources associated with data collection, measure calculation, and reporting systems, and those requiring updates to vendor systems. Depending on the resources available and the time involved in making the necessary changes, the measure may be either revised immediately or suspended until updates to the systems occurs with the measure’s updated specifications.
3.3.5 Recommend a Course of Action

Based on the findings of these steps, the measure developer will recommend a course of action. A discussion of the criteria that form the basis for the disposition decision for each measure and description of the possible outcomes is in the Blueprint content on the MMS Hub, Measure Maintenance.

Depending on the findings from the previous steps, the recommendation may be

- retain
- revise
- remove
- retire
- suspend

3.3.6 Implement the Disposition Action

When proposing measures for revision, suspension, removal, or retirement, the measure developer should evaluate the impact of the decision on the program using the measure when developing the implementation plan. If there are relevant regulatory or rulemaking schedules, the measure developer should include them in the implementation plan. For more information, see the Blueprint content on the MMS Hub, Measure Use, Continuing Evaluation, and Maintenance.

4 CMS CBE Early Maintenance Reviews

The CMS CBE has its own early maintenance review process. Examples of why a measure may require an early maintenance review are

- The evidence supporting the measure, practice, or event has changed, and it no longer reflects updated evidence.
- There is evidence that implementation of the measure or practice may result in unintended consequences.
- There is evidence that use of the measure or practice may result in inappropriate or harmful care.
- There is evidence that measure performance scores may yield invalid conclusions about quality of care (e.g., misclassification or incorrect representation of quality).
- The measure developer made material changes to a currently endorsed measure.

Any party may request a CMS CBE early maintenance review of any measure at any time. The requestor must state the criterion justifying the review and provide supporting evidence. If the CMS CBE determines the need for a review, it notifies the measure steward of the request and indicates the response and format required. If the CMS CBE requests an early maintenance review for a measure supported by the measure developer, the expectation is that the measure developer will respond to the request and be available to address related questions.
5 **KEY POINTS**

The purpose and extent of measure maintenance reviews of quality measures varies depending on the type of review. Measure developers perform three types of measure maintenance reviews:

- annual updates to verify that measure specifications, primarily codes, are up to date
- comprehensive reevaluations at least every 3 years to ensure the measure meets the measure evaluation criteria
- early maintenance reviews when new information about a measure comes to light. In particular, information that may have a significant, adverse effect on the measure or its implementation may precipitate an early maintenance review

Whenever a measure undergoes an annual review or comprehensive reevaluation, the measure developer compares the measure to related or competing measures to assess for harmonization.
REFERENCES


