

Based on the proposed updates to the Endorsement and Maintenance (E&M) Guidebook The Centers for Disease Control and Prevention's National Healthcare Safety Network have the following comments, concerns, and questions:

1). The developer's role in the updated measure evaluation process is unclear.

Under the section "Endorsement Committee Review, Novel Hybrid Delphi and Nominal Groups Technique" on page 19 there is no mention of the developer's role during the endorsement meeting. We suggest adding language to the guide describing a developer's role during the meeting that explicitly states that developers have an opportunity to provide additional information and clarifications when the committee has questions or misunderstands a piece of information in the measure submission.

The evaluation process is no longer transparent. When consensus is not reached on a criterion during independent review, developers will not know why this decision was made. Developers need to have a clear understanding of why the committee did not reach consensus on a criterion so that they can prepare to speak to the issues during the measure decision meeting. Having Battelle staff aggregate independent review results to determine which criteria are consensus not reached does not allow developers to understand the committee responses that led to this result.

2). While the measure evaluation process has decreased the amount of time needed for a measure to receive an endorsement decision, this increases the workload on both committee members and measure developers while potentially decreasing the contribution of subject matter experts to endorsement decisions.

The new process increases the workload on committee members, specifically the expectation that they will perform independent reviews and ratings of all measures. Since Battelle staff create a preliminary analysis and provide their own rating on the measure criteria, committee members are more likely to heavily rely on staff analysis and ratings, rather than reviewing the measure against the endorsement criteria and working to fully understand the measure submission on their own. We recommend staff do not provide ratings of measures in their analyses as this could lead to groupthink. Additionally, as part of the independent review, committee members are now also evaluating any public comments received on the measures along with the staff analysis and the submission itself. There can often be competing opinions between clinical experts, advocacy organizations, and professional associations. Will committee members be given guidance on how to appropriately consider competing interests?

We are concerned with the new committee categorizations, which will result in a decrease in the number of committees and broader topic areas being covered by each committee. We worry that this does not support committees having the appropriate expertise on the Advisory or Recommendations groups. Bringing in subject matter experts to provide insight on specific measure topic areas, such as renal and cancer measures, without allowing them to vote on the measure's overall endorsement is not satisfactory. Those with specific expertise in the topic area that the measure addresses should be full voting committee members and should not just be brought in as subject matter experts who are not allowed to cast an endorsement vote. In addition, the role of the subject matter experts is not currently outlined in the guidebook. If kept, the guidelines of their participation should also be outlined in the guidebook.

Additionally, the minimum number of responses needed to determine consensus is 20, but there is no mention of what happens if 20 independent committee member reviews are not received.

The new process increases the workload on developers. We agree that the equity criterion is important; however, the addition of this criterion creates an added area of analysis that developers must complete without any reduction in other criteria requirements, which are already significantly burdensome. Additionally, a measure can still be important, reliable, and valid even if it does not directly address inequity. This should not necessarily prevent the measure's endorsement. For instance, measures that address healthcare-associated infections (HAI) may not address inequities but are crucial to improve the quality of care all patients receive. We recommend making equity an optional criterion.

3) We are concerned that the committees will not have sufficient overall understanding of the measure evaluation criteria. Past and current committee meetings have shown that committee members do not fully understand how to evaluate the criteria against a measure submission. This lack of understanding regularly occurs with clinicians and measure developers, so it is a real concern that patient and family advocates and representatives on the committees will also not understand the measures, the review criteria, and especially the scientific testing (reliability and validity). Committee members, especially lay members, often benefitted from full committee discussions that were held as part of the former process, and from asking questions of developers and subject matter experts. We would like to better understand the vetting process for committee members, including patient advocates, and to know how they will be trained in the measure evaluation criteria. Additionally, please clarify whether there will be a separate measure evaluation criteria guidebook released later with more detail and specific algorithms to help the committee evaluate the measure against the criteria.

4) Please clarify the differences between the Advisory group and the Recommendations group. It appears that both groups are expected to review and to vote on each measure, and both groups are expected to attend the measure endorsement decision meeting; but the Advisory group is not allowed to discuss the measure or ask questions during this meeting. It seems that having one combined group to review and vote on the measures would better lead to shared comprehension and a more authentic consensus.

5) Please clarify the maintenance schedule: throughout the guidebook there is mention that maintenance review is every three years; however, on page 24 under the "Annual Updates" section it says maintenance review is every five years. We support a five-year maintenance cycle. The work of putting together a submission for endorsement review often begins at least one year prior to the submission deadline. Combined with a six-month process for a measure endorsement decision, a three-year maintenance cycle would mean that half of the maintenance time is spent by developers to prep the new submission. A measure maintenance review every five years would reduce the burden on developers while still ensuring that measures are current.

6) Please confirm when the measure submission questions will be released ahead of a new cycle so that developers can begin preparing their submissions.