Measure Developer Guidebook for Submitting Measures to NQF

VERSION 3.0

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Contents

Introduction

The *Measure Developer Guidebook for Submitting Measures to NQF (Guidebook)* is a resource for measure developers and organizations submitting measures to the National Quality Forum (NQF) for potential endorsement. This updated and revised edition of the *Guidebook* has been expanded to include comprehensive information and guidance about the NQF Consensus Development Process (CDP), evaluation of eMeasures, the SDS Trial Period, and other information that developers need to know when submitting measures to NQF.

The *Guidebook* is organized to provide an overview of NQF goals, priorities, and resources; to guide measure developers and stewards through the seven steps of the CDP; and to provide tips for submitting proposed consensus standards (e.g., measures). The *Guidebook* aims to:

- explain the measure submission and evaluation processes;
- describe the expectations for measure developers and stewards as participants in the process; and
- serve as the main resource for NQF CDP-related processes and policies for measure developers and stewards.

The *Guidebook* will be updated on a timely basis to maintain a current reference to assist measure developers and stewards in navigating the CDP.

National Quality Forum (NQF)

Despite the hard work of many, there is broad recognition that our healthcare system can do a better job on quality, safety, and affordability. NQF is an organization that is honored to be recognized and funded in part by Congress and entrusted with the important public service responsibility of bringing together various public- and private-sector organizations to reach consensus on how to measure quality in healthcare as the nation works to make it better, safer, and more affordable. NQF was established in 1999 and is a nonprofit, nonpartisan, membership-based organization.

NQF has more than 320 organizational members who give generously of their time and expertise. In 2014, more than 883 individuals volunteered on more than 46 NQF-convened committees, working groups, and partnerships. The NQF Board of Directors governs the organization and is composed of key public- and private-sector leaders who represent major stakeholders in America's healthcare system. Consumers and those who purchase healthcare hold a simple majority of the at-large seats.

In 2002, working with all major healthcare stakeholders, NQF endorsed its first voluntary, national consensus performance measures to answer the call for standardized measurement of healthcare services. Over the years, this collaboration across stakeholder groups has resulted in a portfolio of more than 600 NQF-endorsed measures—most of which are in use by both private and public sectors—and an enormous body of knowledge about measure development, use, and quality improvement. Historically, NQF has played a key role in our national health and healthcare improvement priorities. For example, in 2010, NQF convened the National Priorities Partnership to provide input on the first National Quality Strategy in 2010; this partnership has evolved to become the National Quality Partnership, an alliance of our members that

provides opportunities to address complex problems in settings that encourage collaboration, learning, and action. NQF provides public input to the federal government and the private sector on optimal, aligned measure use via its convening of the Measure Applications Partnership. NQF has also advanced measurement science by focusing on topics such as inclusion of sociodemographic factors in risk-adjustment approaches, attribution, and measure variation.

NQF endorses quality performance measures that provide information about the quality of care delivered. The Institute of Medicine's (IOM) widely accepted definition of healthcare quality is "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Institute of Medicine, Medicare: A Strategy for Quality Assurance, Volume I 1990, p.21).

The Department of Health and Human Services (HHS) released the first **National Quality Strategy (NQS**) in 2011. This marked a significant step forward in the effort to align a very fragmented healthcare system. The NQS' aims and goals set forth a unified vision of the healthcare system that was understandable and applicable to all stakeholders at every level—local, state, and national.

The National Quality Strategy—heavily informed by the NQF-convened, private-public National Priorities Partnership—laid out a series of six priorities for focusing the nation on how best and most rapidly to improve our health and healthcare. NQF has carefully aligned its work with these goals, using them as a roadmap for much of its work.

Standardized healthcare performance measures help clinicians and other healthcare providers understand whether the care they offered their patients was optimal and appropriate, and if not, where to focus their efforts to improve the care they deliver. Measures also are used by all types of public and private payers for a variety of accountability purposes, including public reporting and pay for performance. Measures are an essential part of making healthcare more transparent to all, most importantly for those who receive care or help make care decisions for loved ones. Use of standardized healthcare performance measures allows for comparison across clinicians, hospitals, health plans, and other providers.

You can only improve what you measure, so measurement plays a central role in current healthcare quality improvement efforts. NQF endorses measures that are intended for use in *accountability applications* as well as quality improvement. Accountability applications are uses of performance results about identifiable, accountable entities to make judgments and decisions as a consequence of performance, such as reward, recognition, punishment, payment, or selection (e.g., public reporting, accreditation, licensure, professional certification, health information technology incentives, performance-based payment, and network inclusion/exclusion). *Selection* is the use of performance results to make or affirm choices regarding providers of healthcare or health plans.

NQF works closely with measure developers to evaluate measures that meet NQF's evaluation criteria. NQF's criteria have evolved over time to reflect the input of a wide variety of stakeholders and the needs that those stakeholders have voiced with regard to which measures are going to be used to improve the health of patients and hold providers accountable for the care that they deliver. The standard criteria foster consistency and predictability for measure developers and for those using NQF-endorsed measures.

NQF's Portfolio of Endorsed Measures

NQF organizes measures by topic area (i.e., cardiovascular, surgery, safety, etc.). Each topic area has a multistakeholder standing committee that oversees NQF's portfolio of measures. NQF-endorsed measures undergo maintenance of endorsement evaluations approximately every three years. A priority is placed on evaluating related and competing measures at the same time to foster harmonization of endorsed measures. Following the identification of specific national priorities, specific project topics are prioritized and coordinated with available funding.

NQF is looking to work more closely with developers as measures become fully developed and ready for submission to NQF. NQF asks developers to share any information on measures that will be ready for submission within 12 months and inform NQF of any endorsed measures that will be retired. An ongoing dialogue between developers and NQF facilitates planning the various CDP projects and bringing measures into the process as quickly as possible.

NQF's CDP projects consider both newly submitted measures for initial endorsement as well as previously endorsed measures for maintenance of endorsement.

Quality Positioning System (QPS 2.0)

The Quality Positioning System (QPS) is a web-based tool that helps you find NQF-endorsed measures. Search by measure title or number, as well as by condition, care setting, or measure steward. Driven by feedback from users, QPS 2.0 now allows users to provide feedback any time about the use and usefulness of measures and to view measures that are no longer NQF-endorsed, along with other key enhancements. Use QPS to learn from other measure users about how they select and use measures in their quality improvement programs.

Consensus Development Process

NQF uses its formal Consensus Development Process (CDP) to evaluate and endorse consensus standards, including performance measures, best practices, frameworks, and reporting guidelines. The CDP is designed to call for input and carefully consider the interests of stakeholder groups from across the healthcare industry. Because NQF uses this formal Consensus Development Process, it is recognized as a voluntary consensus standards-setting organization as defined by the National Technology Transfer and Advancement Act of 1995 and Office of Management and Budget Circular A-119.

NQF endorsement projects have increased in number and complexity while stakeholder expectations for the timeliness and effectiveness of the entire measure development, testing, and endorsement enterprise have intensified. To be endorsed, a measure submitted to NQF must satisfy four criteria—Importance to Measure and Report (must-pass), Scientific Acceptability of the Measure Properties (must-pass), Feasibility to Implement, and Usability and Use of the Measure Results. Over the past decade, the procedures that form NQF's CDP and its implementation have evolved to ensure that evaluation of candidate consensus standards continues to follow best practices in performance measurement and standards-setting.

Ongoing Enhancements to the Endorsement Process

Since 2000, when NQF first laid out the requirements of measure endorsement into the multistep CDP, NQF has refined the process to address the needs of NQF members and, more broadly, the needs of the healthcare industry. These refinements have targeted the need for new measures; for maintenance of the measures portfolio (e.g., competing and related measure assessments); and for increased efficiency of the CDP (e.g., shorter cycle time from submission to endorsement).

These changes are themselves part of a broader process of continuous improvement in the structure and governance of NQF. They reflect what NQF has learned as the organization has grown, and also respond to the needs of NQF members and more broadly to NQF's multistakeholder constituencies—hospitals, physicians and other clinicians, consumers, purchasers, health plans, government organizations and agencies, suppliers and health industry companies, and quality improvement organizations.

Prior to 2010, NQF conducted maintenance on an ad hoc basis, through topic-specific consensus standards maintenance committees, and through existing projects. As the number of NQF-endorsed measures grew, it became apparent that there was a need to create a more predictable schedule for maintaining the endorsement of NQF-endorsed measures in order for NQF to ensure its portfolio remained current. More specifically, keeping the NQF portfolio current refers to whether measures (1) are appropriately based on current evidence, (2) have scientifically and clinically appropriate specifications, (3) have harmonized specifications, and (4) represent the "best in class" measure for the issue addressed.

To accomplish this goal, in May 2010, the NQF Board of Directors approved a process redesign for measure maintenance and endorsement cycles, according to measure topic. At the three-year cycle review for a topic area, topic/condition-specific committees consider measure endorsement for existing measures, along with newly submitted measures in the same topic area. In addition, NQF put into place processes to ensure that each measure is based on current science, and its accompanying specifications are updated through the annual updates and ad hoc reviews. NQF also implemented a revised process to address harmonization of measures.

Re-examining the Consensus Process

The 2012 hospital-wide readmissions endorsement project raised questions about NQF's process for making endorsement decisions, and specifically how NQF determines that consensus has been achieved. To address these concerns, NQF's Board of Directors created a Consensus Task Force. The charge of this Task Force was to review and recommend enhancements for NQF's CDP. After considering alternatives to reaching consensus and improving the CDP, the Consensus Task Force elected in 2013 to proceed with process changes related to efficiency and incremental efforts to achieve consensus.

Some of the Task Force recommendations were straightforward improvements to the endorsement process that should result in greater transparency and consistency in the process. For example, the Task Force suggested that NQF provide committee members and the public with plain language measure summary documents, develop more detailed educational materials for standing committee members, and limit the exceptions that are made to the submission and evaluation processes.

As part of the Consensus Development Process redesign work, NQF also hosted a four-day Kaizen event focused on measure development and measure endorsement in September 2013. The purpose of the event was to explore ways to provide better, more timely multistakeholder input into the measure development lifecycle that will help develop high-quality measures. A key goal was to reduce the waste and delays across the spectrum—from the measure concept through testing to endorsement—to ensure that the measures that matter are available as soon as possible. Recommendations from the Kaizan have been incorporated into the workflows of the various steps of the CDP.

Revising the Maintenance Process

To streamline and improve the periodic evaluation of currently endorsed measures, NQF updated the evaluation of measures for maintenance of endorsement. This change took effect beginning October 1, 2015. NQF's endorsement criteria have not changed, and all measures continue to be evaluated using the same criteria. However, under the new approach, there is a shift in emphasis for evaluation of currently endorsed measures. Refer to Appendix A for details regarding this change in process.

Endorsement + Designation

NQF's Board of Directors recently approved a set of recommendations put forward by the Intended Use Advisory Panel (Feb 2016). One of these recommendations includes creating a new designation that will identify measures that have exceeded NQF's endorsement criteria in several key areas. Beginning with submissions in the fall of 2016, committees will consider whether a measure recommended for endorsement also meets the "Endorsement +" criteria.

A measure achieving the "Endorsement +" designation will have the following characteristics:

- Meets evidence for measure focus without an exception
- Is reliable as demonstrated by reliability testing of the measure score
- Is valid as demonstrated by empirical validity testing of the measure score (i.e., not via face validity only)
- Is well-vetted in real world settings by those being measured and other users

The first three characteristics were fully defined in the existing evaluation criteria. To address the fourth characteristic of vetting in real world settings, in March 2016, the CSAC approved the addition of another subcriterion under the Usability and Use criteria.

Revising the CDP

Based on comments received from various stakeholders, NQF recognized the need to revise the ratification and appeals procedures of the CPD to eliminate redundant decisionmaking, prevent re-litigation of issues already considered, and reinforce the finality of decisions once appeals are adjudicated. On November 4, 2015, the NQF Board of Directors approved the final changes to the ratification and appeals process. The most significant changes to the process include the following:

- The Consensus Standards Approval Committee (CSAC) will make final measure endorsement decisions, without ratification by another body (i.e., NQF's Board of Directors).

- A newly created Appeals Board will decide measure appeals rather than the NQF Board of Directors.
- Appeals of a measure endorsement decision will go directly to the Appeals Board without a review by the CSAC.

The following section describes the seven steps of the CDP.

Seven Steps of the Consensus Development Process

NQF's CDP involves seven primary steps to endorse consensus standards: call for nominations, call for candidate standards, candidate consensus standard review, public and member commenting, member voting, CSAC decision, and appeals.

Call for Nominations—Standing Committees

NQF strives to continually improve its measure endorsement process to remain responsive to its stakeholders' needs. Volunteer, multistakeholder committees are the central component to this process, and the success of NQF's projects is due in large part to the participation of its standing committee members.

Prior to the HHS contract that started in 2009, NQF operated with much uncertainty regarding resources for proposed projects. Consequently, work was organized on a project-by-project basis with no comprehensive schedule. NQF appointed project-specific steering committees, with the nominations process commencing when project funding had been secured.

Since 2014, NQF has begun seating standing committees for various project topic areas. Committee members will initially serve two-year or three-year terms, and the committees will be responsible for handling endorsement and measure maintenance, as well as ad hoc and expedited project work in their designated areas.

Standing Committee Composition

Topical standing committees include 20 to 25 individuals representing a variety of stakeholders, including consumers, purchasers, providers, health professionals, health plans, suppliers and industry, community and public health, and healthcare quality experts. Because NQF attempts to represent a diversity of stakeholder perspectives on committees, a limited number of individuals from each of these stakeholder groups can be seated onto a committee.

Standing Committee Terms

During the transition from project-specific steering committees to standing committees, committee members will be appointed to a two- or three-year term initially, with approximately half of the committee appointed to a two-year term and the other half to a three-year term. Each term thereafter will be a three-year term. Committee members may serve two consecutive terms. They must step down for a full term (three years) before becoming eligible for reappointment. The committee member's term on the standing committee begins upon selection to the committee, immediately following the close of the roster commenting period.

Standing Committee Expectations and Time Commitment

Participation on the committee requires a significant time commitment. To qualify, prospective committee members should be available to participate in all currently scheduled calls/meetings. Over the course of the committee member's term, additional calls will be scheduled or calls may be rescheduled; new dates are set based on the availability of the majority of the committee.

Nominations are to an individual, not an organization, so "substitutions" of other individuals from an organization at conference calls or meetings are not permitted. Committee members are encouraged to engage colleagues and solicit input from colleagues throughout the process.

The times estimated below may vary depending on the number and complexity of the measures under review as well as the complexity of the topic and multistakeholder consensus process. Committee participation includes:

- Review all measure submission forms (approximately 2 hours per measure)
- Participate in the scheduled orientation call (2 hours)
- For newly seated standing committees, review measures on a workgroup call (2 hours) (*workgroup assignments will be made by area of expertise)*
- Attend scheduled in-person meetings (2 full days in Washington, DC) (*in-person meetings will take place on an annual basis*)
- Complete measure evaluation by reviewing the comments received on the draft report and then participate on the post-comment conference call (2 hours)
- Complete additional measure evaluations by conference call
- Participate in additional calls as necessary
- Complete all surveys and evaluations
- Present measures and lead discussions for the committee on conference calls and in meetings

If a member has poor attendance or participation:

- NQF staff will contact the member and ask if he/she would like to resign from the committee.

If a member is unable to fulfill his/her term (for any reason):

- The nominations received during the most recent call for nominations would be reviewed for a replacement.
- NQF staff will contact the potential replacement.
- If accepted, the new committee member would complete the term of the individual being replaced.
- The out-going member may not select a substitute to carry out the remainder of the term.

Disclosure of Interest

Per the NQF Conflict of Interest Policy for CDP Standing Committees, all nominees will be asked to complete a general disclosure of interest (DOI) form for each committee to which they have applied prior to being seated on the committee. The DOI form for each nominee is reviewed in the context of the topic area in which the committee will be reviewing measures. This form must be completed annually.

Once nominees have been selected to serve on the committee, during the 14-day roster comment period, a measure-specific DOI form will be distributed to determine whether any members will be required to recuse themselves from discussion of one or more measures under review based on prior involvement or relationships to entities relevant to the topic area.

NQF standing committee members are asked to review various types of measures throughout the term of service. Committee members will be asked to complete the measure-specific DOI for all measures under review by the committee to ensure any potential conflicts or biases have been identified.

Standing Committee Application Process

Self-nominations are welcome. Third-party nominations must indicate that the individual has been contacted and is willing to serve. All nominations remain active for one year. To be considered for appointment to the standing committee, please send the following information:

- a completed online nomination form, including:
    - a brief statement of interest
    - a brief description of nominee expertise highlighting relevant experience to the committee
    - a short biography (maximum 750 characters), highlighting experience/knowledge relevant to the expertise described above and involvement in candidate measure development
    - curriculum vitae or list of relevant experience (e.g., publications) *up to 20 pages*
- a completed disclosure of interest form. This will be requested upon submission of a nomination form for committees actively seeking nominees.
- confirmation of availability to participate in currently scheduled calls and meeting dates.

Call for Candidate Standards (Measures or Practices)

At the start of a project, NQF solicits new candidate measures for review and endorsement. Currently, there are two types of calls: call for measures and call for practices. Candidate measures can be used to assess and quantify healthcare processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality care. Practices are defined as specific processes or manners of providing healthcare services or organization-level activities that, when executed, effectively lead to improved outcomes. Measures to be reviewed will include both newly submitted measures and those undergoing scheduled maintenance review.

To submit a measure, a measure steward must complete an online submission form through the NQF website. This step can require significant support from NQF staff who will provide technical assistance and follow-up with stewards and developers.

In addition to new measures, previously endorsed measures are evaluated approximately every three years for maintenance of endorsement. The NQF maintenance team works closely with developers to advise of the timing of submission for measures undergoing maintenance review. NQF will schedule maintenance reviews of related and competing measures together whenever possible. This may require changes to the three-year maintenance review schedule, but developers will not be expected to submit for maintenance review any sooner than 24 months after the prior submission. If you have any questions about the timing of

maintenance review for your measures, please contact the measure maintenance team at measuremaintenance@qualityforum.org.

Submission Deadlines

Deadlines for submitting measures are established by NQF's funding contract(s). Deadlines announced for each topic area will not be extended. The standing committee will evaluate the measure(s) based on the information submitted by the deadline. Additional information will not be accepted unless requested by the committee for measure(s) that are controversial (as determined by discussion and/or close vote of the committee) where additional information could facilitate reaching greater agreement. To ensure transparency, any additional information requested by the committee will be submitted during the public comment period.

Go to this section in this guidebook on creating a good submission and developer resources.

Measure Steward Agreement

Each candidate measure or set of measures has a *measure steward* who assumes responsibility for the submission of the measure to NQF for potential endorsement. The measure steward is responsible for making necessary updates to the measure, and for informing NQF about any changes made to the measure on an annual basis. In addition, the measure steward is responsible for providing the required measure information during the measure maintenance process.

- The measure steward organization is required to identify a single point of contact who will be notified of any upcoming maintenance deadlines or requirements related to the endorsed measure(s).
- Stewards may be contacted by the public and NQF members with inquiries about specifications, updates, and implementation of the endorsed measure(s).
- Stewards are also responsible for maintaining measure details and specifications on any publicly available website.

Each steward who submits a fully specified and tested measure to NQF must submit a completed and signed Measure Steward Agreement (MSA) on or before the project's measure submission deadline in order for the measure to be considered by the committee. The agreement is between NQF and the measure steward and only shared between these parties.

- For new measure stewards, the MSA should be accompanied by the completed addendum, in which the steward must list all the measures (NQF measure number and measure title) being submitted for review.
- For existing measure stewards, only a signed addendum is needed and will be appended to the existing MSA; a new MSA is not required. Contact NQF project staff to receive the addendum.

Only one MSA is necessary per measure steward. If the steward is a governmental organization, an MSA is not required.

See Appendix B for an example of the MSA and Appendix C for an example of the addendum.

Candidate Consensus Standard Review

After the close of a call for candidate consensus standards, the relevant project standing committee will conduct a detailed review of all submitted measures. The duration of a committee's review of the candidate measures for a given project varies, depending on the scope of the project, the number of standards under review, and the complexity of the measures.

As required by the topical area, NQF may use technical experts to provide specific technical advice to the standing committee. NQF also may use the content expertise of other convened standing committees for technical expertise in clinical or cross-cutting areas. While a significant amount of preparatory work, including committee training and initial discussions of measures, occurs via teleconference or webinar, standing committees typically have an in-person meeting for measure evaluation and consideration of harmonization concerns and measure gaps.

Call for Implementation and Pre-evaluation Comments

NQF solicits comments on how NQF-endorsed measures are being used in the field to inform the committee for evaluation of criterion 4 (Usability and Use). Comments may be submitted through QPS or through the NQF project webpage. In addition, NQF also solicits comments prior to the committee's evaluation of measures by opening a 15-day pre-evaluation comment period for both NQF members and the public. All of the comments received through these mechanisms will be provided to the standing committee for consideration prior to their evaluation.

Preliminary Analysis and Ratings by NQF Staff

Prior to release of measure submission materials to standing committees, NQF staff will conduct a preliminary analysis of each measure and assign a preliminary rating for the major evaluation criteria/subcriteria. The purpose of the preliminary analysis is to summarize the salient points of the submission in light of the evaluation criteria, to help committee members navigate the submission form, and to provide additional interpretation and feedback (e.g., regarding the criteria, statistical testing, etc.) as appropriate. The staff's preliminary ratings are not binding on the committees and are meant to serve as input for committee discussion.

Committee Preliminary Evaluations and Workgroup Calls

To facilitate the committee's work, several measures will be assigned to committee subgroups for preliminary evaluation against all criteria and subcriteria. For newly seated standing committees, these subgroups will discuss their assigned measures in two-hour workgroup calls that are held prior to evaluation of the measures by the full committee. Developers are strongly encouraged to participate in these workgroup calls, as this provides an early opportunity for standing committee members to better understand the measures under review and, if necessary, to request additional information from the developer prior to the evaluation by the full committee.

Call and Meeting Agendas

The agendas for calls and meetings for standing committee evaluation of measures will be organized to discuss related and competing measures and harmonization together. Developers should put the meeting and call dates on their calendars early in the project when the dates are first announced.

Standing Committee Meetings

At the in-person or web meeting of the full standing committee, developers will be provided an opportunity to speak briefly about their measures that are under consideration. Each measure developer will be given two to three minutes to introduce its measure(s), and should focus remarks on the rationale/intent behind the submitted measure(s), the approach to measure development and testing, lessons learned from use of the measure, and any unique issues.

The entire committee then determines to what extent the criteria are met for each measure and whether to recommend measures for endorsement. While committee members who conducted the preliminary evaluations will begin the discussion and, when applicable, summarize the workgroup discussions, ultimately, the standing committee as a whole will rate each measure on the measure evaluation criteria and subcriteria.

- Voting by the standing committee during the in-person or web evaluation meeting: A measure is recommended for endorsement by the standing committee when the vote margin on all major criteria (e.g., Importance, Scientific Acceptability) and overall is greater than 60 percent of voting members in favor of endorsement. A measure is not recommended for endorsement when the vote margin on any major criterion or overall is less than 40 percent of voting members in favor of endorsement. The standing committee has *not reached consensus* if the vote margin on any major criterion or overall is between 40 percent and 60 percent, inclusive, in favor of endorsement.

- All measures (recommended, not recommended, and consensus not reached) are put out for public and NQF member comment, after staff summarize the evaluation in a draft report (see below for more information about this comment period). Measures that did not reach consensus in the committee recommendation for endorsement will be labeled as such, and comments are specifically solicited on these measures in the cover memo to the draft report. When consensus is not reached, the committee may request additional information from the developers to address the issues with the measure, to be submitted during the comment period. The standing committee will consider the comments and re-vote on measures where consensus was not reached. The committee will re-vote on any must-pass criteria that had not previously passed by 60 percent. If all must-pass criteria have been passed by the Committee, a vote will be taken on the overall recommendation for endorsement. Members are welcome to re-vote on any other criteria if they would like to do so. After the re-vote(s), only those measures that are recommended (>60 percent in favor of endorsement) by the standing committee will be voted on by the NQF membership.

Developer Request for Reconsideration of a Measure that is Not Recommended

What is a reconsideration?

A reconsideration request is only for measure(s) that are not recommended by the Committee during the in-person meeting, either by failing to pass a "must-pass" criterion or not passing the final, overall vote to recommend for endorsement. The following situations are NOT reconsiderations:

- **Consensus Not Reached (CNR) –** The Committee will re-vote on any measure in which Consensus was not Reached ("CNR measures"). The re-vote IS NOT a reconsideration: it is part of the CNR process.

- **Deferred/additional information requested/conditional voting** – Those measures that may have failed one or more "must-pass" criteria (evidence, gap, reliability, validity), but there is documented discussion between the Committee and developer, with agreement to re-visit some aspect of the measure, typically after additional information is provided by the developer during the public comment period. This IS NOT a reconsideration: it is a continuation of the original evaluation process.

What are the allowable reasons for a developer to request a reconsideration?

The following process for reconsideration will be used to promote consistency, transparency, fairness, and completion of the CDP within project timelines. There are two reasons that may justify a request to reconsider a measure that is not recommended for endorsement:

- REASON 1: NQF's measure evaluation criteria were not applied appropriately
- REASON 2: NQF's consensus development process (CDP) was not followed appropriately

What is the process for requesting a reconsideration?

REASON 1: NQF's measure evaluation criteria were not applied appropriately

- Requests for reconsideration related to inappropriate application of the criteria are submitted **to the Committee** during the public and member comment timeframe. The request must cite the specific evaluation criteria or subcriteria that the developer thinks was not applied properly to the specific information as originally submitted and evaluated by the standing committee.
- The standing committee will review the reconsideration request and rationale, and re-review the cited information and the criteria under question during the post comment call.
- The co-chairs, with the assistance of NQF staff, will direct the Committee discussion to ensure attention to the reconsideration information only and specifically elicit an explanation on how the committee arrived at their original determination in order to assess if the criteria were applied appropriately.
- The Committee then has two options:
  1) The Committee could agree with the developer and trigger a re-vote for the failed criterion and those not voted on.
  2) The Committee could uphold their original vote and would need to document/explain how the criteria was applied appropriately.

As with all measures, the CSAC will determine whether to approve the Committee recommendations.

REASON 2: NQF's consensus development process (CDP) was not followed appropriately

If a request for reconsideration is based on a question of whether the CDP was followed appropriately, a written request for reconsideration must be sent **to the CSAC co-chairs** at least two weeks prior to the CSAC call/meeting that grants endorsement. The process for reconsideration when NQF's Consensus Development Process was not followed is outlined here.

Public and Member Comment

NQF posts all measures on the NQF website for public and member comment regardless of the committee's recommendation (recommended, not recommended, and consensus not reached). The standing committee, with support from NQF staff, considers all comments received.

When a commenting period opens, staff will post a notification on the NQF website, the NQF event calendar, and on the specific project page on the website. NQF staff also sends out an email notification to NQF members and members of the public who have signed up for these notifications.

NQF staff will forward comments to measure stewards/developers as appropriate when the comment raises questions about the measure specifications or when the comment would otherwise benefit from a response from the developer. Because the CDP timeline is tight for this portion of the CDP, NQF typically can allow only five to seven days for the developer to provide a response to the comments. Staff will then compile all of the comments and the developer responses and provide those to the standing committee for consideration during a post-comment call. This will also be posted to the project webpage.

Standing Committee's Consideration of Submitted Comments

During the post-comment call, the standing committee reviews all submitted comments (and developer responses when applicable).

NQF asks that developers attend this post-comment call, which is held a few weeks after the comment period closes. The call is generally one to two hours in length, and developers should be prepared to answer any questions from the committee or public commenters.

After review and discussion of the submitted comments, the standing committee may reconsider their recommendation for (or against) endorsement and/or revise the draft report in direct response to submitted comments. The standing committee is required to re-vote on any measures where consensus was not reached, and is welcome to re-vote on any of the criteria for these measures, if they choose. After all re-votes, only those measures that are recommended (>60 percent in favor of endorsement) by the standing committee will be put out for NQF member vote.

A revised draft report will reflect the standing committee discussion of the comments and all revisions to endorsement recommendations. Should the standing committee determine its revisions to be substantial, a revised version of the draft report may be re-circulated for a second comment period for members and the public. If a revised version of the draft report is re-circulated for a second comment period, the review will follow the same process as the initial review and comment period.

NQF Member Voting

Members of NQF are offered an opportunity to vote on those candidate standards that are recommended for endorsement. Email notification is sent by NQF staff to NQF member organizations, and voting information is posted to the NQF website.

In rare instances, the CSAC may request a second round of member voting. In such cases, NQF follows the same procedure to notify the membership and conduct the voting as outlined in the CDP. All the voting results will then proceed to the next step of the CDP—endorsement by the CSAC.

Endorsement Decision by the Consensus Standards Approval Committee (CSAC)

The Consensus Standards Approval Committee (CSAC), an advisory standing committee appointed by the NQF Board of Directors, is the governing body that has the most direct responsibility for overseeing the implementation of NQF's CDP. The CSAC has a simple majority of consumers and purchasers drawn from a diverse set of healthcare stakeholders, who possess specific expertise in measure development, application, and reporting. The work of the CSAC focuses on NQF's evaluation criteria, endorsement of proposed consensus standards, and the ongoing enhancement of the CDP. The CSAC also serves in an advisory capacity to the Board of Directors and NQF management for emerging issues in performance measurement.

As of early 2017, following comment and voting by the NQF membership, the CSAC will make the final measure endorsement decision, without ratification by another body. The CSAC will review the recommendations of the committee, the comments received, and the results of the NQF member voting. If there is a lack of consensus, the CSAC may seek further input from stakeholder leaders or, on some occasions, may also request a second round of member voting on a particular measure or set of measures.

The CSAC holds three in-person meetings annually (typically in March, July, and November) and convenes monthly by conference call. All meetings are open to NQF members and the public, and audience members have the opportunity to comment on the measures under consideration. Following close of NQF member voting, NQF staff will notify developers of the date that the CSAC will review the measures and will provide developers with the materials for the CSAC call (agenda with dial-in information, CSAC memo, etc.). Developers are expected to attend the call (which is generally one to two hours in duration) or the relevant portion of the meeting, and answer any questions from members of the CSAC. Information about each CSAC meeting is also available on the NQF website, including the meeting agenda and materials and the physical location or dial-in information.

The CSAC also works with staff when there is a request for reconsideration of any measure, in which case staff will act as a liaison between the CSAC, the standing committee, and the measure developer/steward, ensuring communication and cooperation and coordinating activities to complete the project efficiently.

CSAC Criteria for Decisionmaking

To ensure a consistent approach to endorsement decisions, the CSAC identified the following criteria to guide its decisionmaking. The CSAC's rationale for not endorsing a measure that has been recommended by a standing committee and approved by the membership will be documented and communicated to the public.

- **Strategic importance of the measure.** The CSAC will consider the value added by a measure, such as the strategic importance to measure and report on a measure, and assess whether a measure would add significant value to the overall NQF portfolio.

- **Cross-cutting issues concerning measure properties.** The CSAC will consider issues such as harmonization with other applicable measures in the NQF portfolio or risk-adjustment methodology.
- **Adequate consensus across stakeholders.** The CSAC will consider concerns raised by councils and may conclude that additional efforts should be made to address these concerns before making an endorsement decision on the measure.
- **Consensus development process concerns.** The CSAC will consider process concerns raised during the CDP, such as insufficient attention to member comment or issues raised about committee composition.

CSAC Voting

Greater than 60 percent approval for endorsement of a measure by voting CSAC members is required to grant endorsement. A measure is not endorsed when the vote margin is less than or equal to 60 percent of voting CSAC members in favor of endorsement. The CSAC does not have a consensus not reached threshold.

Developer Request for Reconsideration of a Measure that is Not Recommended

If a request for reconsideration is based on a **question of whether the CDP was followed appropriately**:

- Developers may send a written request for reconsideration to the CSAC co-chairs at least two weeks prior to the CSAC call/meeting that grants endorsement, citing the issues within a specific CDP process step, how it was not followed properly, and how it resulted in the specific measure not being recommended.
- Staff will prepare a summary of the CDP process for the measure(s), with special attention to the issues raised and Committee's discussion and explanation, in the reconsideration request.
- The CSAC co-chairs may:
    - uphold the standing committee final recommendation if the process was followed;
    - ask for input from the CSAC, particularly if co-chairs think there is merit to the assertion of not following the CDP;
    - request additional expert input; or
    - if a breach in the CDP was identified, determine if it may have adversely affected the outcome for the specific measure.
- If the CSAC co-chairs determine that a breach in the CDP occurred that may have adversely affected the outcome of the specific measure, then the entire CSAC will evaluate the circumstances and determine a course of action on a case-by-case basis.

Appeals

After a measure has been formally endorsed by the NQF Board, any interested party may appeal the endorsement decision with the NQF Executive Committee (EC) during a 30-day appeal period. An appeal of an endorsed measure must be filed within 30 days of the endorsement decision by going to the project webpage or the searchable list of all NQF-endorsed national voluntary consensus standards. Grounds for an appeal include:

- Procedural errors reasonably likely to affect the outcome of the original endorsement decision, such as a failure to follow NQF's Consensus Development Process (CDP)

- New information or evidence, unavailable at the time the CSAC made its endorsement decision, that is reasonably likely to affect the outcome of the original endorsement decision

For an appeal to be considered by NQF, the appeal must include written evidence that the appellant's interests are directly and materially affected by the measure recently endorsed by NQF, and that NQF's endorsement of this measure has had, or will have, an adverse effect on those interests. All appeals are published on the NQF website.

Appeals are compiled by staff and reviewed by the CSAC. The CSAC evaluates the concern(s) raised and determines if they are relevant and should warrant consideration of overturning the endorsement decision. After discussions, the CSAC makes a recommendation to the NQF EC regarding the appeal. EC's decision on an appeal of endorsement is published on NQF's website.

Project staff will notify developers when the appeals period will open and close, and at the close of the appeals period, staff will notify developers if any appeals were submitted on their measure(s). If an appeal was submitted, staff may request developers (if necessary) to provide a written response to the issues outlined in the letter of appeal. The letter of appeal will be discussed at the next CSAC meeting (whether an in-person meeting or conference call). The CSAC will review and discuss the letter of appeal and the developer's written response. The appellant will be asked to speak to their concerns, and the developer will be provided an opportunity to respond. The developer will be asked to attend the CSAC call (about one to two hours in duration) and to answer any questions from the CSAC. Following the CSAC call, staff will notify the developer of the CSAC's recommendation to the NQF EC and will notify the developer of the EC's decision on the appeal.

The New Appeals Process

In August 2016, NQF implemented changes to its appeals process that were initiated and approved by its Board of Directors. Central to these changes is the Board's call for NQF to establish a five-member Appeals Board that will be responsible for adjudicating all submitted appeals regarding measure endorsement decisions. ***These changes apply to NQF measure endorsement projects with in-person meetings scheduled after August 2016***.

The newly, constituted Appeals Board, composed of NQF Board members and former CSAC and/or committee members, will adjudicate appeals to measure endorsement decisions without a review by the CSAC. The decision of the Appeals Board will be final.

All submitted appeals will be published on the NQF website. Staff will compile the appeals for review by the Appeals Board, which will evaluate the concern(s) raised and determine if the appeal should warrant overturning the endorsement decision. Decisions on an appeal of endorsement will be publicly available on NQF's website.

Throughout the process, project staff will serve as liaisons between the CSAC, the Appeals Board, the committee, developers/stewards, and the appellant(s) to ensure the communication, cooperation, and appropriate coordination to complete the project efficiently.

Submitting Measures to NQF

NQF endorses performance measures as voluntary consensus standards. Interested stewards and/or developers of performance measures may submit their candidate standards for consideration by NQF. To submit a performance measure, a steward must complete and electronically submit the online measure submission form for each measure that it wishes to submit to NQF for consideration.

Online Submission

To submit a measure for consideration, a measure steward must complete and submit the online form through the NQF website prior to the project's measure submission deadline. **The questions in the online submission request the information needed by the standing committee to evaluate the measure against the criteria.** NQF has many resources to describe the background and rationale of the measure evaluation criteria. Developers should familiarize themselves with these documents to present their measures in the best light.

The online submission form includes a variety of features and allows the users to:

- Gain secure access to the submission form from any location with an internet connection
- Save a draft version of the form and return to complete it at their convenience
- Print a hard copy of the submission form for reference

Microsoft Word Forms for Evidence and Testing Information

The required information for **criterion 1a Evidence** and **criterion 2 Testing** use Word forms rather than the online form. Word forms allow developers to include tables and other formatting options that are not possible in the online form. The Word forms are available on the submitting standards webpage.

To review the questions included in the submission forms, review a Word version of the online form on the NQF website. The majority of quality performance measures will use the standard submission form; however, there are two special types of measures—*cost and resource use measures* and *composite measures*—that have separate forms to capture information about their unique characteristics.

Submission of eMeasures

The Measure Evaluation Criteria and Guidance requires that *eMeasures* meet all of the existing endorsement criteria. The criteria make the following clarifications that are specific to eMeasures:

- A new eMeasure version of an endorsed measure is not considered an endorsed measure until it has been specifically evaluated and endorsed by NQF. *An eMeasure should be submitted as a separate measure even if the same or a similar measure exists for another data source (e.g., claims or registry).*

- eMeasures must be in Extensible Markup Language (XML) files that are compliant with the accepted version of the Health Quality Measures Format (HQMF) schema. eMeasures created using the Measure Authoring Tool (MAT) are compliant with this schema.
- eMeasure developers must use value sets that are vetted and published through the National Library of Medicine's Value Set Authority Center (VSAC) to reduce implementation issues related to value sets and code system validation and to encourage the use of harmonized value sets. If eMeasures use value sets that have not been vetted through the VSAC, the submission should include a detailed rationale for not using value sets that are not vetted and stored in the VSAC. Additionally, each value set should use a nationally recognized clinical terminology standard that is current, and its purpose statement should be completed in the VSAC.
- Documentation of testing on more than one Electronic Health Record (EHR) is required to establish Scientific Acceptability, indicating that the measure data elements are repeatable and valid and that the measure score can be accurately calculated.
- For "respecified" eMeasures that are currently used in federal programs (known as "legacy" eMeasures), the developer may use an alternate method for testing if the standard method (testing in more than one EHR) proves to be difficult. The developer can use the "Bonnie" testing tool (bonnie.healthIT.gov) to simulate the testing of the eMeasure in an electronic environment. The developer will need to create test patient data banks that correspond to each component of the measure logic and simulate the use of the measure against those data sets. A description of the test patient data banks and the output from the Bonnie tool (which is only currently available through screen shots) must be sent to NQF for evaluation.
- Submissions will require an eMeasures Feasibility assessment to ensure that data elements and measure logic can be used to interpret the eMeasure specifications unambiguously. See the Submitting Standards webpage to view the updated template for the Feasibility Assessment.

eMeasure Approval for Trial Use

Developers have indicated that it can be challenging to test eMeasures to the extent necessary to meet NQF endorsement criteria until the eMeasures have been more widely implemented. At the same time, there is interest in developing eMeasures for use in federal programs and obtaining NQF endorsement for those eMeasures. NQF endorsement may provide the impetus to implement measures; however, if a submitted measure with very limited testing does not meet NQF endorsement criteria, it could be prematurely abandoned.

In 2014, NQF piloted *eMeasure Approval for Trial Use* for eMeasures that were ready for implementation but could not be adequately tested to meet NQF endorsement criteria. NQF used the multistakeholder consensus development process to evaluate and approve for trial use several eMeasures that addressed important areas for performance measurement and quality improvement, although they did not have the requisite testing needed for NQF endorsement. Those eMeasures were assessed to be technically acceptable for implementation. The goal for approving eMeasures for trial use was to promote implementation and the ability to conduct more robust reliability and validity testing that can take advantage of clinical data in EHRs.

In April 2015, the CSAC agreed to make approval for trial use available for all eMeasures submitted to NQF. Approval for trial use is NOT time-limited endorsement as it carries no endorsement label. Measures approved for trial use will be so indicated in QPS.

SDS Trial Period

In 2014, the NQF Board of Directors approved a two-year trial period to allow for inclusion of sociodemographic factors in risk-adjustment approaches, for prior to making it a permanent change in NQF policy. Beginning in April, 2015, and throughout the duration of the trial period, the NQF policy that prohibited use of SDS factors in statistical risk-adjustment models has been suspended, and NQF is implementing several of the Risk Adjustment Expert Panel's recommendations.

Instructions for Providing Required Information During the NQF SDS Trial Period

These instructions are applicable to all health outcome measures, patient-reported outcome based performance measures [PRO-PMs], and intermediate outcome measures, and potentially applicable to some process measures.

- Enter patient-level sociodemographic variables that were available and analyzed during measure development in section **1.8** of the Measure Testing Attachment. These variables could include:
    - Patient-reported data (e.g., income, education, language)
    - Proxy variables when sociodemographic data are not collected from each patient (e.g., based on patient address and use of census tract data to assign individual patients to a category of income, education, etc.) and conceptual rationale for use
    - Patient community characteristics (e.g., crime rate, percent vacant housing, smoking rate, level of uninsurance) assigned to individual patients for the specific community where they live (not in the community in which the healthcare unit is located)
- If you ARE risk-adjusting your measure, in addition to the conceptual/clinical and statistical methods and criteria used to select patient risk factors, enter the conceptual description (logical rationale or theory informed by literature and content experts) of the causal pathway between the patient sociodemographic factors, patient clinical factors, quality of care, and outcome in section **2b4.3** of the Measure Testing Attachment. If you are NOT risk-adjusting your measure, include discussion of, and data for, sociodemographic factors as part of the rationale and analysis included in section **2b4.2** of the Measure Testing Attachment.
- Enter the analyses and interpretation resulting in a decision to include or not include SDS factors in section **2b4.4b** of the Measure Testing Attachment. This analysis could include:
    - Variation in prevalence of the factor across measured entities
    - Empirical association with the outcome (univariate)
    - Contribution of unique variation in the outcome in a multivariable model
    - Assessment of between-unit effects versus within-unit effects to evaluate potential clustering of disadvantaged patients in lower quality units
- Enter reliability and validity testing for the measure as specified in section **2a2** and **2b2** of the Measure Testing Attachment.

  - If changing from a non-SDS-adjusted risk-adjustment model to one that is SDS-adjusted, then updated reliability and validity testing is required and must be entered into section 2a2 and 2b2 of the Measure Testing Attachment.
- Enter a comparison of performance scores with and without SDS factors in the risk-adjustment model in section **2b6** of the Measure Testing Attachment.
  - In section **2b6.1**, enter the method of testing conducted to compare performance scores with and without SDS factors in the risk adjustment model for the same entities. Describe the steps and the statistical approach used.
  - In section **2b6.2**, enter the statistical results from testing the differences in the performance scores with and without SDS factors in the risk-adjustment model. (e.g., correlation, rank order)
  - In section **2b6.3**, provide an interpretation of your results in terms of the differences in performance scores with and without SDS factors in the risk-adjustment model for the same entities. What do the results mean, and what are the norms for the test conducted?
  - NOTE: If the measure has more than one set of specifications/instructions (e.g., one for medical record abstraction and one for claims data), then section 2b6 must also be used to demonstrate comparability of the performance scores.
- If a performance measure includes SDS variables in its risk adjustment model, the measure developer must provide the information required to stratify a clinically-adjusted-only version of the measure results for those SDS variables in section **S.10** in the Measure Submission Form. This information should include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate.
- Enter the details of the final statistical risk model and variables in section 2b4.1.1 of the Measure Testing Attachment.

Frequently Asked Questions about the SDS Trial Period

What are sociodemographic status (SDS) factors?

Sociodemographic status refers to a variety of demographic (e.g., age, primary language, household income, zip code) and socioeconomic factors (e.g., income, education, occupation).

What is risk adjustment?

Risk adjustment is a statistical approach that allows patient-related factors (e.g., comorbidity and illness severity) to be taken into account when computing performance measure scores for the purpose of comparing healthcare providers (e.g., hospitals and clinicians). Because patient-related factors can have an important influence on patient outcomes, risk adjustment can improve the ability to make accurate and fair conclusions about the quality of care patients receive.

What is a conceptual relationship? What factors are necessary for a committee to consider SDS adjustment?

A conceptual relationship refers to a logical theory or rationale that explains the association between an SDS factor(s) and the outcome of interest. The conceptual basis may be informed by prior research and/or healthcare experience related to the measure focus, but a direct causal relationship is not required (i.e., it could be a direct cause, an indirect cause, or serve as a surrogate for a cause for which data are lacking).

Assessment of the conceptual relationship between an SDS factor and a measure's focus includes a consideration of whether the effect of the SDS factor is primarily mediated by the quality of care delivered (i.e., does the SDS factor affect the outcome independent of the quality of care delivered? Or does the SDS factor lead to the delivery of inferior care processes, which in turn affects the outcome?) For example, while a patient's income level may affect his or her ability to use post-acute care services, and therefore might potentially be considered in the risk adjustment approach for a readmissions measure, a patient's income level is unlikely to affect his or her likelihood of experiencing a complication during hospitalization, so would it be inappropriate to include income as a factor in the risk-adjustment approach for a hospital-acquired infection measure.

If a conceptual relationship exists between an SDS factor and the measure focus, empirical testing should be conducted to confirm that relationship. The empirical analyses should include the details of the final risk-adjustment approach.

What is NQF's SDS trial period?

For two years, NQF will conduct a trial of a temporary policy change that will allow inclusion of SDS factors in the risk-adjustment approach for performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent.

What prompted the SDS trial period?

Previous NQF policy prohibited the inclusion of SDS factors in risk-adjustment approaches out of concern that doing so might conceal inequalities in care and result in lower standards of provider performance for certain subpopulations. The Centers for Medicare & Medicaid Services (CMS) contracted with NQF to examine this policy and the broader issue of SDS risk adjustment. In 2014, NQF convened a multistakeholder panel of experts in healthcare performance measurement and disparities to consider if, when, and how performance measures should be adjusted for SDS. After its deliberations, the Expert Panel recommended that NQF should allow inclusion of SDS factors in the risk-adjustment approach for performance measures when conceptual reasons and empirical evidence demonstrate that it is appropriate. The NQF Board of Directors reviewed the Expert Panel's recommendations and decided to temporarily change NQF's policy and evaluate its impact during the course of a two-year trial period.

Which measures are affected?

Starting April 2015, any new measure submitted for possible endorsement or any endorsed measure that is undergoing maintenance review will be included in the SDS trial. Each measure must be assessed individually to determine if SDS adjustment is appropriate. Along with an assessment of the conceptual relationship between an SDS factor and a measure focus of interest, measure developers should also provide information on patient-level SDS factors (either individual or contextual) that were available and analyzed during measure development. If a performance measure is SDS-adjusted, the measure developer must also include specifications for stratification of a non-SDS-adjusted version of the measure.

Who will review the measures for the potential need for SDS adjustment?

As part of their measure evaluation for potential endorsement, NQF standing committees will examine each measure submitted to their project to determine if there is agreement with the risk-adjustment approach used by a measure developer.

How will measures be evaluated during the trial period?

With the restriction against SDS adjustment lifted, standing committees and other stakeholders will be able to raise questions about SDS risk factors in their evaluation of performance measures submitted to NQF for initial or continued endorsement. Where there is a potential conceptual basis for SDS adjustment, the standing committee will evaluate whether the developer assessed SDS factors according to the guidelines for selecting risk factors recognized by the NQF Expert Panel. In addition, the standing committee will consider the utility of the SDS factors that are available, the developer's analyses and interpretation regarding the importance of SDS factors in their risk-adjustment model, and comparison of performance scores with and without SDS adjustment.

What about previously endorsed measures not undergoing maintenance review?

A potential need for risk adjustment for SDS factors can serve as the basis for an ad hoc review. Ad hoc reviews can be requested by any party. Requester(s) should indicate which criterion the ad hoc review should address and include adequate written evidence to justify the review. Measures undergoing an ad hoc review will be evaluated by the relevant standing committee using NQF's ad hoc measure review process. If inclusion of SDS factors in the risk-adjustment approach is the basis for an ad hoc review, developers will be asked to submit a revised testing attachment in order to provide additional information on the conceptual and empirical relationship of the risk-adjustment variables to the measure focus.

Can lack of SDS adjustment affect the decision regarding endorsement?

Yes. If a standing committee determines that risk adjustment for SDS factors is both conceptually and empirically appropriate for a particular measure, lack of that adjustment can be grounds for not recommending the measure for endorsement. This applies to both new and previously endorsed measures evaluated in regular projects as well as to measures considered through the ad hoc evaluation process.

How will the trial period affect the All-Cause Admissions/Readmissions project?

In 2014, NQF's Executive Committee ratified the recommendations of the NQF-Board appointed CSAC to endorse 17 admissions/readmissions measures that were under review at that time, but only if specific conditions were met. One of these conditions requires that these endorsed measures be returned to the All-Cause Admissions and Readmissions Standing Committee to determine which of the 17 measures should be included in the trial period. In April 2015, the Committee agreed that 15 of the 17 measures should be included in the trial.

How will the trial period affect the Cost and Resource Use project?

Similar to the measures in the recent admissions/readmissions project, the NQF Executive Committee ratified the CSAC's recommendation to endorse three cost measures, with the condition that they be considered for inclusion in the trial period. This condition for endorsement of the cost measures will be addressed via an ad hoc review of the measures by the Cost and Resource Use Standing Committee in a timeframe agreed upon with the measure developer.

How will NQF evaluate the success of the trial period?

NQF is committed to making the process and outcomes transparent to all stakeholders throughout the trial period. The primary focus of evaluation during the trial period is to ensure that NQF structures and processes support committees and stakeholders in identifying performance measures that should and

should not be adjusted for SDS. This will include descriptive information about the trial period, evaluation of relevant NQF structures and processes, and qualitative feedback from measure developers, standing committee members, NQF members, and members of the public.

The NQF Disparities Standing Committee is charged with reviewing the implementation of the revised NQF policy regarding risk adjustment for SDS factors and with evaluating the SDS trial period. At the end of the two-year trial period the Disparities Standing Committee will make a recommendation to CSAC and the NQF Board of Directors about whether or not the policy prohibiting SDS factors in the risk adjustment models of NQF-endorsed measures should be reinstated or if NQF should continue to allow these factors to be considered.

What impact will inclusion of SDS factors in risk-adjustment approaches have on payment and provider behavior?

Questions that require the use of SDS-adjusted measures cannot be answered in a relatively short trial period. Information on the impact of SDS-adjusted measures on payment and provider behavior will be available only after the measures are implemented and the resulting data are collected and reported over time. As a result, we will not be able to address these longer-term questions during the two-year trial period. The primary focus of evaluation during the trial period is to ensure that NQF structures and processes support committees and stakeholders to identify performance measures that should and should not be adjusted for SDS.

Table 1: Sociodemographic Factors PROs and CONs

(excerpted from the NQF Technical Report: Risk-Adjustment for Socioeconomic Status or Other Sociodemographic Factors)

Factors/Concepts (specific variables)	**PROs**	**CONs**	**Caveats**
Factors that should be considered, depending on data availability and the specific outcome or process			
Income	• Allows for use of various ranges	• Hard to collect privately (e.g., in clinician office) • Not easily collected with a single question • May not be an acceptable question to all patients • Meaning is not geographically consistent due to difference in costs of living	• For national performance measures, need to consider standardization to account for area wage and cost of living differences

Factors/Concepts (specific variables)	**PROs**	**CONs**	**Caveats**
Income in relation to federal poverty level	• Definition is standard • Being used under ACA • Researchers are used to using it	• Doesn't include receipt of other benefits (e.g., food stamps) • Doesn't account for cost of living or community offsets	
Household income	• May be more meaningful than individual income	• Requires assessment of household size	
Medicaid status as proxy	• Relatively easy to collect in claims data	• Eligibility not consistent across states	• Potentially becomes more useful as more states expand Medicaid to 138% federal poverty level
Social Security Supplemental Income (SSI)		• Correlated with Medicaid status, but not consistently across states	• In many states, receipt of SSI automatically makes one eligible for Medicaid
Education	• Perceived to be valid (i.e., less misreporting than for income) • Definitions fairly consistent across various subgroups (e.g., answers from immigrants comparable to those from others) • Fairly stable across time, at least after a certain age	• Not widely collected by healthcare units • If collected (e.g., in EHR text fields) may not be easily retrievable	

Factors/Concepts (specific variables)	**PROs**	**CONs**	**Caveats**
Homelessness	• Strongly associated with health outcomes • Measures something "beyond" income • Current Housing and Urban Development (HUD) definition	• Multiple other definitions • Data often not collected • Status can change	• Prevalence tends to cluster among safety net healthcare units
Housing instability	• May be better indicator than homelessness which can change	• More difficult to define than homelessness	
English proficiency	• Standard definition exists • Tied to need for translation services/other resource needs and therefore should be collected • Increasingly being collected (required by "Meaningful Use" and some states)		
Insurance status	• Readily available • Some indication of access and resources • Benefit coverage strongly related to affordability	• Wide variability in insurance coverage • Data for underinsurance not widely collected	
Medicaid status	• Readily available • Some indication of limited income and resources	• Not consistent across states	

Factors/Concepts (specific variables)	**PROs**	**CONs**	**Caveats**
No insurance	• Readily available • Standard meaning		• Difficult to capture information about these patients (particularly if using claims data)
Community/ neighborhood-level data used as proxy for individual data or as contextual variable	Many variables available from Census data • Income • Education • Immigration status • Language • Unemployment • Home ownership • Single parents • Others	• Census data do not include all potentially important variables • Residential heterogeneity will affect whether it is a good proxy for data about individuals. • Heterogeneity may differ based on levels of socioeconomic segregation and potentially population density. • Requires geocoding for Census Tract and smaller areas.	
Contextual– proportion vacant housing	• Seen as indicator for other related issues such as poverty, crime, lack of resources		
Contextual–crime rate	• May be an indicator for other related issues such as poverty, lack of resources		

Factors/Concepts (specific variables)	**PROs**	**CONs**	**Caveats**
Other factors that could be considered			
Social Support	• Some brief items have been used in previous research • Captures something that other variables do not	• Multidimensional construct that typically requires multiple questions • Lack of agreement about how to measure • Not consistently measured	
Living alone	• Available in OASIS data for home health	• Directionality may not be consistent. In some situations such as frailty or impairment, it could be a risk factor. In other situations, it might be an indicator of ability to live alone due to good health and function.	
Marital status	• Often collected		
Occupation	• May capture other concepts (e.g., environmental exposures)	• Multiple definitions • Potentially large data collection burden due to the complexity of the concept • Marginal value (i.e., over and above that contributed through use of other variables) may be limited • Unclear how to handle certain population subgroups (e.g., retirees, students, homemakers)	

Factors/Concepts (specific variables)	**PROs**	**CONs**	**Caveats**
Employment status	• Often collected	• Employment status does not reflect income or availability of insurance • Simple yes/no does not reflect desire/happiness with situation (e.g., retirees may be happy to be unemployed) • Subject to change requiring continuous updating	
Literacy	• This concept may also be able to partially capture health literacy	• No standardized definitions • May be easy to game	If the correlation with education is high, then education could be used.
Health literacy	• Potentially more relevant to healthcare • Three-item and single-item validated questions exist	• Not consistently collected/ available	
Local/state funding for safety net providers (e.g., tax base)	• Affect resources available to safety net providers beyond insurance	• Data not easily collected/ available	• Not a patient characteristic • Risk for unintended consequences (setting a lower standard for poorly supported institutions might send the wrong messages to tax payers)
Race/ethnicity	• Correlated with SES and may be more available than other variables	• May be more correlated with bias	• Should not generally be used as proxy for SES

Harmonization

The current quality landscape contains a proliferation of measures, including some that could be considered duplicative or overlapping, and others that measure similar but not the same concepts and/or that define patient populations somewhat differently. Such duplicative measures and/or those with similar but not identical specifications may increase data collection burden and create confusion or inaccuracy in interpreting performance results for those who implement and use performance measures.

Resolving issues around harmonizing measures and handling competing measures remains one of the key challenges in NQF measure endorsement projects. Our process for implementing NQF's Harmonization and Competing Measures process is described in the Information for Developers report of January 2013. Developers must respond to the questions about harmonization in their measure submission.

ICD-10

HHS implemented conversion to ICD-10 coding on **October 1, 2015**. Further details explaining the changes can be accessed at http://www.cms.gov/Medicare/Coding/ICD10/index.html?redirect=/icd10.

NQF requires ICD-10 codes to replace any ICD-9-CM codes for all new submissions, measures undergoing endorsement maintenance, and measures due for annual update.

ICD-10 Requirements

If a new measure is developed and tested using ICD-10 codes the following **does not apply**.

For measures that have converted ICD-9 to ICD-10 codes please include in your submission:

- A statement of intent for the selection of ICD-10 codes, chosen from the following:
  - Goal was to convert this measure to a new code set, fully consistent with the intent of the original measure.
  - Goal was to take advantage of the more specific code set to form a new version of the measure, but fully consistent with the original intent of the measure.
  - The intent of the measure has changed.
- Excel spreadsheet, including:
  - Full listing of ICD-9 and ICD-10 codes, with code definitions
  - The conversion table (if there is one)
- Description of the process used to identify ICD-10 codes, including:
  - Names and credentials of any experts who assisted in the process
  - Name of the tool used to identify/map to ICD-10 codes
- Summary of stakeholder comments received

New Measures or Measures Undergoing Maintenance Previously Using ICD-9 Codes

Include ICD-10 codes in Numerator Details, Denominator Details, and/or Exclusion Details as appropriate.

- **Requirement 1** is satisfied by including one of the sentences in the documentation of requirement 3 for new measures and measures undergoing maintenance.
- **Requirement 2** is satisfied by attaching Excel files at data field **S.2b. Data Dictionary or Code Table**.

- **Requirement 3** can be documented in the Validity section, data field **2b2.2** in the **Measure Testing Submission Form**. If ICD-10 testing results are available, enter those into the Validity section at data field **2b2.3** in the **Measure Testing Submission Form**. If necessary, document a webpage URL or attach a Word or PDF file in the data field **A.1. Supplemental Materials**.

Annual Update

Include ICD-10 codes (with definitions) in Numerator Details, Denominator Details, and/or Exclusion Details as appropriate.

- **Requirement 1** is satisfied by an entry in the **Release Notes** section of the Annual Update Form.
- **Requirement 2** is satisfied by attaching Excel files at data field **S.2b. Data Dictionary or Code Table**.
- **Requirement 3** requires that a Word or PDF document be e-mailed to **measuremaintenance@qualityforum.org** when submitting the Annual Update.

Guidance

See http://www.qualityforum.org/publications/2010/10/ICD-10-CM/PCS_Coding_Maintenance_Operational_Guidance.aspx

Measure Submission Completeness Checklist

Developers are also encouraged to follow the checklist below to ensure the measure submission is complete and responsive prior to Standing Committee consideration.

- ☐ Measure steward agreement or concept agreement is completed and signed, and attached to the submission.
- ☐ Conditions for submission are addressed.
- ☐ There are responses in all fields on measure submission form (MSF) (including the Evidence and Measure Testing Attachments).
- ☐ Testing should be conducted for the data source(s) and level(s) of analysis for which the measure is specified; information for data source and level of analysis should be consistent across the specifications items (S.17, S.20) and the testing attachment items (section 1.1 and 1.4).
- ☐ Attachments include eMeasure specifications (S.2a); data dictionary/code list (S.2b); Evidence and Measure Testing attachments.
- ☐ All URLs are active and accurate.
- ☐ Harmonization/competing measures: Did you present a plan for harmonization of the related/competing measures identified by staff during early identification/triage? (see Harmonization process)
- ☐ Paired measures should be submitted on separate forms.
- ☐ An eMeasure must be submitted in HQMF format.
- ☐ Composite measures (which contain individual measures with a single score) are submitted on a composite form and responses to the composite measure questions are included.

- ☐ Both ICD-9 and ICD-10 codes included, if applicable.

Technical Assistance

NQF project staff will provide technical assistance to measure developers at any time before or during the measure submission process. Contact the project team with any questions about the criteria, how to answer the questions in the form, any technical issues with the online submission process, or anything else!

How to Create a Good Submission

NQF has many resources for developers that provide helpful tips on creating a good submission:

- ***What Good Looks Like! - Measure Submission Examples (2013)***. For examples of the type of information NQF is seeking in the measure submission forms, review the *What Good Looks Like!* document on the submitting standards webpage. NOTE: If possible, we will update this document to reflect our most current submission forms.

Additional Developer Resources

The NQF website (**www.qualityforum.org**) has a number of resources for measure developers. To start, below are useful links:

Submitting Standards Webpage

This page contains information and resources for submitting your measure(s) to NQF. http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx

Maintenance of Endorsement Webpage

This page contains information on what happens after a measure is endorsed by NQF.

Measure Developer Webinars

A monthly measure developer webinar is held on the third Monday of each month. Topic areas for these webinars include NQF's evaluation criteria, updates on policies and processes, and other subjects, as determined with input from measure developers. Each month, details of webinars are posted to NQF's web calendar. Developers may email measuremaintenance@qualityforum.org to be added to the distribution list for the measure developer webinar.

Project Webpages

As each project begins, a webpage is created on the NQF website: http://www.qualityforum.org/Projects.aspx. From your NQF dashboard, you can register to follow any project.

Alert Lists for CDP Projects

NQF has also created alert lists for our CDP projects. Sign up on the project page to receive an email notification of upcoming calls/meetings, deadlines, and the open and close date of each step. (These lists are intended for interested stakeholders (not developers) submitting measures to a particular project; each project has a developer-specific e-mail list to receive project notifications.)

Measure Developer Advisory Panel

NQF has formed a Measure Developer Advisory Panel to solicit feedback and suggestions to improve our maintenance and endorsement activities. Members convene via conference call or webinar on a monthly basis. For more information about this group, contact measuremaintenance@qualityforum.org.

Call for Measure Concepts

NQF and many stakeholders are intensely interested in learning about measures under development (i.e., "the pipeline"). NQF encourages developers and end-users of performance measures to submit concepts to NQF in any topic area through NQF's new Measure Inventory Pipeline. This will serve as an important source of information for HHS and other stakeholders on new measure development in the broader healthcare community. The pipeline will also enable NQF to track current and planned measure development to ensure early collaboration among developers to drive harmonization and alignment of measures. **These concepts will not be evaluated by NQF**; however, standing committees may use the information submitted to help inform their harmonization and measure gaps discussions. It will also enable NQF to track current and planned measure development to ensure early collaboration among developers to drive harmonization and alignment of measures.

In an effort to capture comprehensive information on measures in development, NQF seeks input on several variables including:

- Measure description
- Numerator statement
- Denominator statement
- Planned use
- Stage of development
- Other relevant information

NQF's Measure Inventory Pipeline has been available for concept submissions since November 2013.

Maintenance of Endorsement

As an endorsing body, NQF is committed to ensuring that the NQF-endorsed performance measures continue to meet the rigorous NQF measure evaluation criteria. Maintenance of endorsement encompasses several processes: (1) annual updates to measure specifications of endorsed measures, (2) endorsement maintenance projects, (3) ad hoc reviews, (4) analysis and guidance for methodological and technical challenges, and (5) education and technical assistance to measure developers on endorsement maintenance activities. As the science of measurement and the uses of measures have evolved, NQF has worked continually to improve its evaluation and endorsement processes to meet the needs of stakeholders involved in performance measurement and improvement.

Annual Updates

Every year when an endorsed measure is not being re-evaluated for continued endorsement, measure stewards will submit a status report of the measure specifications to NQF. This report will either reaffirm

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 changes occur to a measure at any time in the three-year endorsement period, the measure steward is responsible for informing NQF immediately of the timing and purpose of the changes. An ad hoc review will be conducted if the changes materially affect the measure's original concept or logic (see below).

Ad Hoc Review

The ad hoc review process was last updated as of August 1, 2016.

Definition: An ad hoc review is a formal measure evaluation and endorsement reconsideration outside of the scheduled maintenance of endorsement process. An ad hoc review is limited and focused on a specific issue regarding an evaluation criterion and is not the same as a maintenance of endorsement evaluation.

Ad Hoc Triggers

An ad hoc review may be triggered in a variety of ways:

1. A material change to an endorsed measure is submitted by a measure developer during an annual update. A material change is defined as any modification to the measure specifications that significantly affects the measure result such as:

    a. a change to the population being measured (e.g., changes in age inclusions, changes in diagnoses or other inclusion criteria, changes in excluded populations)

    b. changes to what is being measured (e.g., changes in target values like blood pressure or lipid values)

    c. inclusion of new data source(s); or

    d. expanding the level of analysis or care settings

    Examples of material changes include:

    - Adding a new variable or deleting an element/component of the numerator/denominator or inclusion/exclusion specifications
    - Change in the timeframe of the measure (e.g., all patients last year versus all patients this year and last year)
    - Change to the age groups in the measured population
    - The addition or deletion of an diagnostic code that is not merely an update, but that represents a different or new classification/category
    - A change in the risk-adjustment approach (e.g., from risk-stratification to a model-based approach) or the addition or deletion of a variable in the risk-adjustment approach (e.g., inclusion of an new SDS factor)

    The following are not considered to be material changes:

    - Updating codes, to reflect current coding nomenclature for a specific condition, disease,

procedure, test, or drug
- Adding a new drug to a family of drugs already specified in the measure
- A change in the risk adjustment involving a modification to the value of a coefficient. (e.g., the statistical model remains the same, but new data updates the relationships among the variables, so that the estimates of the coefficients change)
- Clarifying or adding a clarifying detail to a numerator or denominator, inclusions or exclusions, or other specification elements that does not change the measure result
- Documenting an exclusion that already existed in the measure's algorithm would not be a material change to a measure that already excluded it, but did not document it as an exclusion.)

When submitting revisions to measure specifications during annual updates developers must provide a response to the following questions in the release notes:

- Why was the change in specifications made?
- How does the change in specifications affect the measure results?

If a material change in the specifications is identified, data from re-testing of the measure with the new specifications is required for the ad hoc review.

2. Directive by the standing committee or the CSAC to review a specific criterion sooner than the scheduled maintenance of endorsement evaluation.

3. Request by a developer or third party. An ad hoc review can be requested at by any party, as long as there is adequate evidence to justify the review.

Ad Hoc Review Process

1. The NQF measure maintenance team will review all annual updates for material changes. If none are identified, the annual update will be accepted. If material changes are identified, the measure maintenance team will notify the developer and schedule an ad hoc review.

2. An ad hoc review directed by the standing committee or the CSAC will be carried out by the NQF project team with assistance from the measure maintenance team as needed.

3. Each request for an ad hoc review is reviewed by NQF's measure maintenance team, which includes clinical experts and methodologists. Any request for an ad hoc review must be submitted online via the Quality Positioning System (QPS) or via email at measuremaintenance@qualityforum.org. Requests must indicate which criterion the ad hoc review should address and include adequate written evidence to justify the review. Multiple criteria can be used in the justification. The criteria are:

    - the evidence supporting the measure has changed (e.g., for risk-adjusted measures, evidence of conceptual relationship between socioeconomic and other social demographic factors (SDS) and the measure's performance)

- implementation of the measure results in unintended consequences
- material changes have been made to the measure (including changes to the measure's setting and data source).

The ad hoc review process follows an abbreviated version of the CDP and includes:

- Evaluation by a relevant topic-specific standing committee (If the relevant topic-specific standing committee has not been constituted, NQF will post a call for nominations for technical experts to conduct the ad hoc review.)
- Public and member comment period for no less than 10 days
- Review and final endorsement decision by the CSAC; and
- An appeals period

An ad hoc review may be carried out at the same time as an active endorsement maintenance project. The measure under ad hoc review will follow the timeline of the active project.

If a measure remains endorsed after an ad hoc review, it is still subject to its original maintenance cycle.

Appendix A: NQF's Measure Evaluation Criteria

NQF endorses performance measures that are suitable for both accountability applications (e.g., public reporting, accreditation, performance-based payment, network inclusion/exclusion, etc.) as well as internal quality improvement efforts. NQF's *measure evaluation criteria and subcriteria* are used to determine the suitability of measures for use in these activities. Because endorsement initiates processes and infrastructure to collect data, compute performance results, report performance results, and improve and sustain performance, NQF endorsement is intended to identify those performance measures that are most likely to facilitate achievement of high-quality, efficient healthcare for patients. The criteria and subcriteria also relate to the concept of "fitness for purpose." For example, the clinical evidence should support use of a measure with a specific target patient population (e.g., foot care for patients with diabetes), and testing of the measure as specified indicates under what circumstances reliable and valid results may be obtained (i.e., using the measure with a specified data source and level of analysis or for the accountable entity for which performance is being measured).

Throughout the various iterations of the NQF measure evaluation criteria, the basic concepts and criteria have remained largely unchanged. However, the measure evaluation guidance—which focuses on the specificity and rigor with which the criteria are applied—has become more comprehensive and more specific over time. The guidance on measure evaluation is intended first for standing committees that evaluate performance measures and make recommendations for NQF endorsement, as well as the NQF project staff who assist them. Second, the guidance informs measure developers about how to demonstrate that a measure meets the criteria. Third, the guidance informs NQF members and the public about how measures are evaluated and informs those who use NQF-endorsed performance measures about what endorsement means.

The most current version of the criteria and guidance (dated August 2016) incorporates several updates to the evaluation criteria and consolidates several NQF documents pertaining to the criteria and evaluation into a single document, as follows:

- Subcriterion 1a. Includes additional guidance for patient-reported outcome measures and appropriate use measures.
- Subcriterion 1b. Opportunity for improvement. Guidance has been expanded to discuss "topped out" measures and NQF's policy for Inactive Endorsement with Reserve Status. Additionally, guidance is provided for assessing gap for low incidence patient safety events and mortality measures.
- Subcriterion 1c. High Priority was removed as an evaluation criterion by the CSAC.
- Subcriterion 2b4 Risk adjustment: In late 2014, the NQF Board of Directors approved, for a trial period, a change in the policy that prohibited the use of sociodemographic factors in risk-adjustment approaches. During the trial period, risk-adjusted measures submitted to NQF for evaluation should be submitted with analysis of both clinical and nonclinical (including SDS) factors considered for inclusion in risk-adjustment models. Details on the SDS Trial Period are included.
- Guidance for evaluating eMeasures has been included.

- Criteria and guidance for population-level measures and access measures are included.
- An "any-or-none" measure will no longer be considered a composite measure. "All-or-none" measures will continue to be classified as composites.
- An additional subcriterion under Usability and Use—4d. Vetting by those being measured and others— is one of the criteria used to determine whether a measure meets criteria for the "endorsement +" designation.

Revised Maintenance Process

Under the revised approach to the evaluation of currently endorsed measures, there is a shift in emphasis for several of the evaluation criteria/subcriteria, as follows:

- **Evidence:** If the developer attests that the evidence for a measure has not changed since its previous endorsement evaluation, there is a decreased emphasis on evidence, meaning that the Committee may accept the prior evaluation of this criterion without further discussion or need for a vote. This applies only to measures that previously passed the evidence criterion without an exception. If a measure was granted an evidence exception, the evidence for that measure must be revisited.
- **Opportunity for Improvement (Gap):** For re-evaluation of endorsed measures, there is increased emphasis on current performance and opportunity for improvement. Endorsed measures that are "topped out" with little opportunity for further improvement are eligible for *Inactive Endorsement with Reserve Status*.
- **Reliability**
    - Specifications: There is no change in the evaluation of the current specifications.
    - Testing: If the developer has not presented additional testing information, the Committee may accept the prior evaluation of the testing results without further discussion or need for a vote.
- **Validity:** There is less emphasis on this criterion if the developer has not presented additional testing information, and the Committee may accept the prior evaluation of this subcriterion without further discussion and vote. However, the committee still considers whether the specifications are consistent with the evidence. Also, for outcome measures, the committee discusses questions required for the SDS Trial even if no change in testing is presented.
- **Feasibility:** The emphasis on this criterion is the same for both new and previously endorsed measures, as feasibility issues might have arisen for endorsed measures that have been implemented.
- **Usability and Use:** For re-evaluation of endorsed measures, there is increased emphasis on the use of the measure, especially use for accountability purposes. There also is an increased emphasis on improvement in results over time and on unexpected findings, both positive and negative.

Other Guidance Resources

Other guidance documents that are, for the most part, still current include:

eMeasure Feasibility Assessment report (2013)

Composite Measure Evaluation Guidance Report (2013)

Patient Reported Outcomes Report (2012)

Usability Report (2012)

Harmonization Guidance and Definitions (2013)

For a historical view of NQF's measure evaluation criteria and guidance, please see the following reports:

Review and Update of Guidance for Evaluating Evidence and Measure Testing: A Technical Report (2013)

Evidence Task Force Report (2011)

Measure Testing Task Force Report (2011)

Competing Measures Report (2011)

Measure Harmonization Report (2011)

Reserve Status Report (2011)

Draft eMeasure Testing Guidance (2012)

Guidance on Quality Performance Measure Construction (2011)

Appendix B: Measure Steward Agreement

MEASURE STEWARD AGREEMENT

BETWEEN
NATIONAL QUALITY FORUM
AND

_____

This **MEASURE STEWARD AGREEMENT** (the "Agreement") is entered into by and between National Quality Forum ("NQF") and _____ ("Steward"), effective upon NQF's acceptance of the Agreement.

WHEREAS, NQF is a nonprofit organization whose mission is the improvement of the quality of American healthcare; and

WHEREAS, the evaluation of healthcare performance measures through an endorsement process is part of that mission; and

WHEREAS, Steward wishes certain healthcare performance measures to be considered for endorsement; and

WHEREAS, NQF and Steward (collectively, the "Parties") wish to acknowledge and agree upon the terms for bringing forward such healthcare performance measures for endorsement consideration;

NOW, THEREFORE, in consideration of the foregoing, NQF and Steward agree as follows:

I. Definitions

A. **"Measure"** means a healthcare performance measure submitted by Steward for endorsement. Any reference in this Agreement to "Measure" means each healthcare performance measure submitted by the Steward for consideration for endorsement by NQF.

B. **"Fee-Based Measure"** means a Measure that requires the use of a grouper, risk adjustment, other methodology or any component that is not publicly available or free of charge and is essential to calculating the Measure.

C. **"Permitted Use"** means the use of a Measure for any of the following purposes:

1. calculating, reporting, or displaying of Measure results to:
    a. the public, free of charge; or
    b. public and private purchasers of, and payers for, healthcare related service and products; or
    c. federal, state, or local regulatory programs and regulators.

2. improving or auditing the internal performance of an organization or individual where the improvement or audit is performed by such organization or individual.

II. Submission of Measure

A. Steward submits Measure for endorsement on a voluntary basis and agrees to comply with NQF's processes for Measure submission and endorsement, as may be amended from time to time.

B. Steward will submit the Measure(s) that are subject to this Agreement according to a process prescribed by NQF, including but not limited to an electronic method. Any such measures are incorporated by reference into this Agreement.

III. NQF Review of Measure

A. NQF will review Measure in accordance with its Measure endorsement process and criteria. Steward acknowledges that NQF's process and criteria for Measure endorsement may change over time. Steward acknowledges that NQF's endorsement decision depends upon Steward's full disclosure of information about the Measure.

B. If NQF proposes changes to a Measure prior to initial endorsement, NQF shall notify the Steward of the proposed changes, and the Steward shall have the right to accept such changes or reject the changes and withdraw the Measure from consideration for initial endorsement. If NQF proposes changes to a Measure during maintenance review, NQF shall notify the Steward of the proposed changes, and the Steward shall have the right to accept such changes or reject the changes and NQF may remove endorsement of the Measure undergoing maintenance review. If Steward withdraws the Measure from consideration for initial endorsement or maintenance review for any reason, NQF shall have no right to endorse the original or modified Measure unless Steward elects to re-submit the original or modified Measure.

C. NQF, in its sole discretion, determines whether to endorse a Measure. Steward or a third party may appeal a decision to endorse a Measure through NQF's appeals process. The result of an appeal of a Measure endorsement decision is final.

D. In order to maintain endorsement, Steward must cooperate with the measure maintenance process, which occurs approximately every three (3) years.

IV. Disclosure of Measure Details

A. Measure Disclosure Prior to Endorsement. Measure disclosure to NQF prior to endorsement means disclosure of complete information regarding the Measure to NQF's staff, directors, committee members, its agents, and the public for the purpose of evaluation, analysis, or display of the Measure in connection with NQF endorsement, including but not limited to:

1. detailed measure specifications, including codes with descriptors, algorithms/measure logic, and risk adjustment model;
2. information supporting the usability and use of the measure;
3. information supporting the feasibility of the measure;
4. evidence supporting the measure focus;
5. data and results generated from testing the measure; and
6. for a Fee-Based Measure, the proposed price structure for the grouper, risk adjustment, other methodology or component that is essential to calculating the Fee-Based Measure.

B. Measure Disclosure Following Endorsement Decision.

1. Endorsed Measure. If the Measure is endorsed, NQF may disclose, display publicly and make available in any format it chooses:
   a. complete information regarding the Measure, including all information disclosed by the Steward under Section IV.A;
   b. the Measure Submission Form;
   c. all updates to the Measure; and
   d. a link from NQF's website to the Steward's website.
2. Rejected or Withdrawn Measure. If the Measure is not endorsed, or the Steward withdraws an unendorsed Measure from the evaluation process, NQF may disclose, display publicly and make available in any format it chooses:
   a. complete information regarding the Measure, including all information disclosed by the Steward under Section IV.A;
   b. the Measure Submission Form; and
   c. the reason why the Measure was not endorsed.
3. Measure Endorsement Removed. If NQF removes Measure endorsement or the Steward withdraws an already-endorsed Measure, NQF may disclose, display publicly and make available in any format it chooses:
   a. complete information regarding the Measure, including all information disclosed by the Steward under Section IV.A;
   b. the Measure Submission Form; and
   c. the reason why Measure endorsement was removed or the Measure withdrawn.
4. Survival. This Section IV.B. shall survive the expiration or termination of this Agreement.

V. Conditions of Endorsement

A. Steward must make the Measure specifications generally available for Permitted Uses, free of charge and on a non-discriminatory basis. Steward must make a Fee-Based Measure available for Permitted Uses according to the pricing structure submitted as part of the endorsement process and shall notify NQF if the Steward imposes a fee or charge that is inconsistent with the pricing structure submitted at the time of endorsement. In connection with a Fee-Based Measure only, Steward may require a user to enter into a no-cost non-disclosure or licensing agreement in order to use the Fee-Based Measure for a Permitted Use.

B. Steward must maintain the Measure throughout the period of endorsement. Steward's failure to maintain the Measure may result in the removal of endorsement.

C. If Steward changes a Measure following endorsement, Steward must notify NQF of the changes as soon as practicable and make them available to the public free of charge. A change to a grouper, risk adjustment, other methodology or similar component in a Fee-Based Measure must be made available to the public and any charge for such component must be reasonable.

D. Steward agrees to cooperate with ad hoc reviews. Triggers for ad hoc reviews include, but are not limited to, a material change in a Measure or a change in evidence supporting the Measure.

E. Steward may refer to a currently endorsed Measure as "NQF-endorsed." Steward agrees to comply with guidelines that NQF may issue in connection with publicizing the status of the endorsed measure.

VI. Term and Termination.

A. This Agreement is effective as of the date above written and shall have a term, with respect to each Measure brought forward for endorsement under this Agreement, from the date of submission for endorsement until a given Measure is up for maintenance, unless this Agreement is otherwise terminated.

B. NQF may terminate this Agreement with respect to a given Measure upon ten (10) days written notice of its decision to remove endorsement of such Measure. NQF shall notify Steward of the reasons for removing endorsement and provide Steward with a reasonable opportunity to address the reasons for removing endorsement. The determination of whether Steward has sufficiently addressed such reasons, as well as the determination to remove endorsement, shall be made in NQF's sole discretion.

C. If Steward requests that NQF remove endorsement of a Measure or the Steward withdraws an unendorsed Measure from the evaluation process, this Agreement will terminate with respect to that Measure upon the effective date of endorsement removal or the date the unendorsed Measure is removed from the evaluation process.

D. If Steward does not wish to continue as Steward of a Measure, Steward must provide written notice to NQF as soon as practicable following such decision and such Measure will be handled in one of the following ways:

a. Steward may request removal of endorsement from the Measure as described in Subsection C of this Section VI;

b. Steward may transfer stewardship of the Measure to an identified organization according to NQF process and the Steward will have no responsibility for such Measure;

c. Steward may authorize NQF to search for a replacement steward; or

d. NQF may remove Measure endorsement.

E. If Steward does not maintain the Measure and does not respond to NQF's inquiries regarding the Measure, NQF may, in its discretion, search for a replacement steward or remove endorsement from the Measure.

VII. Indemnification and Liability.

A. Steward shall hold NQF harmless and indemnify NQF for any and all costs, damages, and expenses, including reasonable attorneys' fees, incurred by NQF and arising out of: (i) any claim, action, suit or allegation that the Measure or use thereof infringes or constitutes a misappropriation of any trademark, patent, copyright, trade secret, proprietary right or similar property right, or (ii) any claim, action, suit or allegation that is based on Steward's negligence or willful misconduct related to the Measure.

B. Steward waives any claim against NQF and releases NQF from any liability arising from a decision to endorse, decline to endorse, or remove endorsement of a Measure.

C. Steward acknowledges that information regarding Steward's Measure(s) and displayed by NQF is only as accurate as the information provided by Steward. Steward waives any claim against NQF and releases NQF from any liability resulting from inaccurate display of information regarding Steward's Measure(s) unless such inaccuracy is a result of NQF's gross negligence or willful misconduct. Any such damages shall be limited to actual damages.

D. This Section VII shall survive the expiration or termination of this Agreement.

VIII. Miscellaneous.

A. Any notice or other communications under this Agreement must be in writing and will be considered given on the date delivered to the other party through a method capable of tracking. Notices shall be sent to:

National Quality Forum
1030 15th Street, NW
Suite 800
Washington, DC 20005
ATTN: Office of General Counsel

B. This Agreement may only be amended in writing through a document signed by both Parties.

C. The Parties will attempt to resolve any disputes between them through negotiation or other informal means. In the event that a dispute cannot be resolved in this manner, the Parties will submit to binding arbitration in accordance with the rules of the American Arbitration Association. This subsection shall survive the expiration or termination of this Agreement.

D. This Agreement will be governed by and construed in accordance with the laws of the District of Columbia, without reference to conflicts of law provisions. This subsection shall survive the expiration or termination of this Agreement.

E. The undersigned each respectively represents that each party is authorized to sign this Agreement on behalf of the Parties to this Agreement.

IN WITNESS WHEREOF, the Parties sign below to indicate their acceptance of this Agreement.

NATIONAL QUALITY FORUM

_____	_____
Signature of Authorized Representative	Signature of Authorized Representative
_____	_____
Name of Authorized Representative	Name of Authorized Representative
_____	_____
Title of Authorized Representative	Title of Authorized Representative
_____/_____/_____	_____/_____/_____
Date	Date

MSA completion tips.

- The Steward's name must appear in the first paragraph next to the phrase — "The Steward," which appears in parentheses after the Steward's name.
- The Steward's name MUST match the Steward's name on the underlying MSA. The individual signing the Addendum on behalf of the Steward need not be the same individual who signed the MSA.
- The document must be signed and dated by the steward. Digital signatures are acceptable. Electronic "signatures" in cursive font do not constitute a digital signature.

Appendix C: Addendum of the Measure Steward Agreement-New Measures

ADDITION OF MEASURES FOR
CONSIDERATION FOR ENDORSEMENT
ADDENDUM TO MEASURE STEWARD AGREEMENT
BETWEEN
NATIONAL QUALITY FORUM
AND
_____

This Addendum to the **MEASURE STEWARD AGREEMENT** (the "Agreement"), which was entered into on ____/_____/_____ by and between National Quality Forum ("NQF") and _____ ("Steward"), is effective upon acceptance by NQF.

WHEREAS, Steward has entered into the Agreement and wishes to submit additional Measures for consideration for endorsement;

NOW, THEREFORE, in consideration if the foregoing, NQF and Steward agree as follows:

I. **List of Measures**. Steward lists below additional Measures for consideration for endorsement by NQF:

Measure #	Measure Title	Steward

II. **Miscellaneous.**

A. All capitalized terms in this addendum have the same meaning as those in the Agreement.

B. This Addendum is incorporated by reference into the Agreement. All other provisions of the Agreement remain unchanged.

IN WITNESS WHEREOF, the Parties sign below to indicate their acceptance of this Addendum.

NATIONAL QUALITY FORUM

_____	_____
Signature of Authorized Representative	Signature of Authorized Representative
_____	_____
Name of Authorized Representative	Name of Authorized Representative
_____	_____
Title of Authorized Representative	Title of Authorized Representative
_____/_____/_____	_____/_____/_____
Date	Date