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January 20, 2012

National Quality Forum 1020 15 Street, N.W. Suite 800 Washington, DC 20005

RE: Expedited Review of All Condition, All Cause Readmissions Measures

Dear Dr. Corrigan:

On behalf of our nearly 5,000 member hospitals, health systems and other organizations, , the American Hospital Association (AHA) appreciates this opportunity to comment on the allcondition readmission measures currently under Expedited Review. These measures are potentially important to a wide variety of health care stakeholders. Consumers are being encouraged to use these measures to assess hospitals' ability to successfully treat patients and prevent complications that would bring them back to the hospital. Payers, including Medicare, may choose to use them for payment incentives or to tier networks of providers. Providers are expected to use them to monitor their ability to appropriately transition patients to the next level of care.

The readmission measures are intended to draw attention to readmissions that could and should have been prevented through appropriate action on the part of the health plan (in the case of the National Committee for Quality Assurance measures) or the hospital (in the case of the Centers for Medicare & Medicaid Services (CMS)/Yale measure). This is an incredibly complex and challenging task because not all readmissions could or should have been prevented, as the Steering Committee discussed. Readmissions are caused by a host of factors and involve the actions of not only hospitals but other care providers, and of the patients and their families, payers and policymakers.

Clearly, hospitals have a responsibility for taking appropriate actions to ensure patients do not need to be readmitted when those admissions are preventable. Hospitals understand their responsibility for addressing these issues and are eager to have a good measure, or set of measures, that appropriately assesses how well they are doing in preventing those readmissions they can. But if the measures do not include adequate exclusions or risk adjustments that recognize the fact that some readmissions are planned and appropriate and others are the result of something outside the scope of what a hospital or a health plan can manage, then the measures create confusion, limit hospitals' ability to identify real opportunities for improvement and prompt others to unfairly judge the performance of hospitals.



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Because the causes of readmissions are complex and public policy makers and payers are eager to put National Quality Forum (NQF) endorsed measures to use quickly, it is critically important that the measures advanced through the NQF process have a thorough and fair review. NQF has put in place processes to ensure that happens through the Consensus Development Process – a process that has been in use for several years and that includes specific timeframes for input of stakeholders into the work of the Steering Committee and for voting – is meant to ensure this review takes place.

The Expedited Review

Anticipating that there may be occasions on which there is an urgent need for a measure to meet a legislated or regulatory mandate, the NQF board adopted a policy by which an expedited review could be authorized. This is the first project for which an expedited review has been undertaken and, understandably, we are all learning how it works and identifying opportunities for clarification. Nonetheless, the AHA is disappointed that the necessary authorization for the expedited review that is called for in the board-adopted policy was apparently not obtained to initiate this project and that NQF did not investigate whether there was, in fact, a legislative or regulatory mandate that necessitated the expedited review in accordance with the stated criteria. **We do believe that this request did not, in fact, meet the NQF's criteria for an expedited review for the reasons articulated below.**

Further, we observe that the expedited review process had a dilatory effect on the work of the Steering Committee. The process prevented Steering Committee members from having a full and open discussion of whether the measures met all of the NQF endorsement criteria, precluded the measure developer from providing as full and thoughtful a set of responses as it might have wished to address many of the issues the Steering Committee raised, and impinged on the Steering Committee's ability to undertake a full and substantive review of the analyses the measure developer was able to produce during the course of the Steering Committee meeting or in the week that followed. In turn, the materials provided in the report for review by NQF members and the public are less clear and meaningful than they should be to enable us to fully understand and comment on the content of the report and discussions.

In the end, the public and NQF members are being asked to comment on measures that the Steering Committee believes have substantial flaws, as indicated by the less than unanimous vote to recommend these measures be brought forward. That recommendation was made only on the presumption that further changes will be made to the measures over the next year, and that even more substantial changes are expected within the next three years.

An expedited review, by design, curtails the time allotted for the Steering Committee to review measures, for the public and members to comment, for NQF members to vote, and for the Consensus Standard Approval Committee (CSAC) to process the measures and make its decision. These shortened timeframes abridge everyone's ability to effectively participate in the multi-stakeholder discussion and consensus process that is the fundamental reason for the NQF's existence. As a member of the NQF from its inception, the AHA believes in the importance of the multi-stakeholder consensus process and values the opportunity to participate in it. We believe that the opportunity for all interested stakeholders to fully participate in the review of the proposed measures and the Steering Committee's decisions, and to thoughtfully exercise our right to comment and vote on the measures, should not be abbreviated except in those rare instances when there is a clear and compelling need.

The NQF board appears to have been similarly concerned that Steering Committee, member and public input not be curtailed without sufficient justification. The board tasked the multi-stakeholder decision-making body, the CSAC, with making the determination that the criteria for expedited review had been met. Because the CSAC is multi-stakeholder, it brings a wide variety of perspectives to such a critical decision, including the perspectives of individuals from all of the different NQF councils. Further, the NQF board laid out three criteria, all of which must be met, to justify the expedited review. These are detailed in the NQF's September 23, 2010 board-adopted policy as follows:

- 1. The extent to which the measures under consideration have been sufficiently tested and/or in widespread use;
- 2. Whether the scope of the project/measure set is relatively narrow; and
- 3. Time-sensitive legislative/regulatory mandate for the measures.

We searched for the CSAC minutes or a transcript documenting the discussions of why the CSAC believed this request met the stated criteria, but we learned from staff that the CSAC as a whole never discussed the appropriateness of this request *vis a vis* the articulated criteria and that no set of minutes or transcript exists to review. Further, there is no documentation in the Steering Committee report concerning the rationale for having granted an expedited review or how CMS's request was judged to meet the board-established criteria. We are puzzled about how one would effectively judge measures against the first two criteria, but we are clear that the third criterion has not been met.

Extent to which the measures have been sufficiently tested and/or are in widespread use. Of the three measures submitted for this review, one has been in broad use (the NCQA plan level measure). For the other two (the CMS/Yale measure and the United measure) a judgment had to be made that they had been "sufficiently tested." There are no details in the board-adopted policy that would enable the developers or anyone else to readily understand what is meant by "sufficiently tested." Additionally, there is nothing included in the draft report that would allow us to understand what factors were considered in making the judgment that these measures had been tested and were ready to move forward. We think it is valuable for individuals other than the measure developer to have had the opportunity to test the measure's performance and be able to discuss its strengths and weaknesses before it is proffered for endorsement as a national standard. We believe that testing by someone other than the developer should be required for a measure to be considered "sufficiently tested," but we recognize that others may have a variety of views on what constitutes sufficient testing. At this juncture, we simply urge that the NQF board consider providing additional detail on what it means by "sufficiently tested" to bring greater clarity to the decisions on what qualifies for expedited review. Further, we think it is appropriate that a description of how the measures being brought forward meet this criterion should be included in the CSAC minutes of the approval of the expedited review and in the report of the Steering Committee so that all interested stakeholders can fully understand why their opportunity to participate in the process, to comment and to vote has been curtailed.

<u>Narrow scope of project/measures</u>. Similarly, we believe more information is needed so that all may have a common understanding of what the board meant when it said the "scope of the project/ measures set is relatively narrow." To most hospitals, looking at readmissions for

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virtually all of the patients admitted to the hospital is not a "narrow" undertaking. It requires consideration of and decisions on a wide variety of conditions that may or may not be included in the list of exclusions or rolled into the risk adjustment factors, and other such decisions – literally hundreds of decisions about the construct of the measures that lead to different results depending on what decision is made. We thought that a measure that potentially touches on every patient admitted to a hospital would be considered broad, but we understand that others may have different perspectives and **urge the NQF board to provide a better articulation of what it means** by "relatively narrow" to ensure the policy is implemented as the board intended.

<u>A time-sensitive or regulatory mandate</u>. It is clear that the measures included in this project do not meet the time-sensitive requirement. Documents from the early part of this project, such as the Call for Measures, indicate that CMS requested the expedited review to use the measure in complying with Sections 3025 and 3026 of the *Patient Protection and Affordable Care Act* (ACA). Section 3025 establishes a readmission penalty for Medicare payments and Section 3026 creates a Care Transition assistance program. Section 3026 provides funding for community based organizations that are working in partnership with hospitals to assist in reducing readmissions, but it does not call for the creation of new measures. Instead, it requires the use of measures adopted by the Secretary under Section 3025. For purposes of this discussion, Section 3025 is the relevant section.

Section 3025 of the law instructs the Secretary to initiate the readmissions penalty program beginning in fiscal year (FY) 2013 using condition- or procedure-specific readmission measures. Specifically, it instructs the Secretary to begin with the acute myocardial infarction (AMI), heart failure and pneumonia readmission measures that have been endorsed by NQF. Beginning in FY 2015, the Secretary is instructed to expand the readmission measures to the four conditions identified by Medicare Payment Advisory Commission (MedPAC) as important, which are chronic obstructive pulmonary disease, coronary artery bypass grafts, percutaneous transluminal coronary angioplasty and other vascular conditions. The Secretary also may expand the list of conditions on which she is measuring to include readmissions for additional conditions or procedures she deems to be important. All of the language of the provision calls for condition-specific or procedure-specific readmission measures; there is no language indicating that an all-condition readmission measure is desired or appropriate for this policy. Further, the Secretary is instructed that the measures shall take into account "through risk adjustment or other methods" exclusions for readmissions that are unrelated to the prior discharge. At the Steering Committee meeting, Yale expressly acknowledged that its measure did not take into account unrelated readmissions. For all of these reasons, this measure does not meet the requirements of Section 3025 and, thus, this cannot be the justification for an expedited review, as I noted at the Steering Committee meeting.

Dr. Helen Burstin subsequently notified me that CMS's justification for an expedited review was not Section 3025, but instead was Section 10303 of the Affordable Care Act; it is this section that is cited in the report as providing the justification. Section 10303 directs the Secretary to develop and periodically update provider-level outcome measures for hospitals, physicians and other providers she determines to be appropriate. The outcome measures are to address "acute and chronic diseases including, to the extent feasible, the five most prevalent and resource-intensive acute and chronic medical conditions..." There is nothing in this section that speaks to a need or desire for an all-condition measure. There is nothing in this section that directs the use

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of these measures in any program or indicates any time sensitivity with regard to their adoption in a program. The only time constraints articulated in law are for the <u>development</u> of the measures and their periodic update. We are not suggesting that the department should develop the required measures and let them lie fallow. However, **Section 10303 provides no justification for the expedited review by NQF of these measures because there is no timesensitive legislative mandate for the endorsement or use of the measures and there is no indication that Congress sought development of generic, all-condition readmission measures.** Instead, it very clearly anticipated condition- or procedure-specific readmission measures.

The lack of time for reviewing these critically important measures is not merely an inconvenience. As previously articulated, the time pressure for reviewing these measures impinged on the work of the Steering Committee and is making it much more challenging for NQF members and other stakeholders to provide meaningful input, particularly since this report is out for review at the same time as other critical documents, such as the perinatal measures report and the Measure Applications Partnership report. We believe it is within the authority of the CSAC to review the justification for an expedited review in this matter, and if the CSAC agrees with us that an expedited review was not appropriate because the criteria for expedited review was not followed, then we suggest there may be several steps that could be taken to provide some relief:

- The CSAC could consult with the chairs and members of the Steering Committee to determine if it would be beneficial to bring the group back together for another meeting for a fuller discussion of the issues raised during the first in-person meeting. The Steering Committee's discussions could be further informed by the comments that have been received during this truncated review process.
- Members and the public should be granted additional time for review and comment on these measures. If the Steering Committee is to be reconvened and might, as a result, alter any of the original decisions and recommendations, we urge that there be a second public comment period that commences with the reissuance of the Steering Committee's revised recommendations. If the Steering Committee is not reconvened, we urge that the current comment period be extended another 30 days and that NQF widely publicize the new opportunity for review and comment, organize member calls whereby members can discuss the document and their areas of concern and agreement, and make available information from the measure developers that clarifies and explains the materials that are currently appended to the report.
- Finally, we urge that the CSAC make the normal timeframe available for voting on this report.

Characteristics of the Measures

During the course of the in-person meeting, there was considerable discussion about the scientific acceptability of the measures, with a number of critical questions being raised regarding the data sources, the risk adjustment calculation, the integrity of the data reported for small volume hospitals, and other critical questions. In light of the short timeframe available for this review, we have not had the opportunity to identify and convene members with expertise in

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this area who could provide further insight and extend the committee's insights into many of these questions. Thus, there are only two areas on which we are able to offer comments at this juncture:

the importance of including socioeconomic factors in the risk adjustment methodology; and
 the usability of the measures.

<u>Socioeconomic factors</u>. On the first day of its in-person meeting, the committee had a lively discussion regarding the inclusion of socioeconomic factors in the CMS/Yale measure. There is, in fact, a growing list of publication describing both the relationship between low socioeconomic status and readmission rates. As the Steering Committee discussed, this adjustment for socioeconomic factors reflects the fact that poor communities have substantial health care and other infrastructure deficits, and while hospitals can and should do all within their power to care for and assist the patients in these impoverished communities, they cannot overcome all of the problems in a community. For example, some communities have greater challenges with regard to access to appropriate foods such as fresh fruits and vegetables, fish or chicken, and low sodium ingredients for meals. Other communities have few pharmacies, primary care providers, mental or substance abuse treatment facilities, and physical therapy or other rehabilitation facilities. They may lack good public transportation systems to enable patients to get back and forth to medical treatments and a variety of other needed services that are useful to patients recovering from hospitalizations.

The measure developer apparently asserted that there was no need to adjust for socioeconomic factors because some of the hospitals serving a very high proportion of Medicaid patients (a proxy for low socioeconomic status) had lower rates of readmissions than some of the hospitals serving a very low proportion of Medicaid patients and shared a tabular form of the data in the chart on the next page. While the developer's statement is about the ability of some hospitals to succeed despite the challenges of serving an impoverished community is true, it is not sufficient justification for failing to adjust for the impact of socioeconomic status. Some hospitals serving a very sick population of patients also are able to achieve a lower rate of readmissions than those hospitals serving a less acutely ill set of patients, but no one suggests that justifies the elimination of the adjustment for differences in the acuity of illness. Instead they realize that the high-performing hospital with a high level of patient acuity is likely worth studying and emulating because it has figured out how to succeed despite obstacles. The hard work of those hospitals against the odds is recognized and appropriately lauded, not ignored.



Similarly, those hospitals serving under-resourced communities have a much more challenging time preventing unnecessary readmissions. It is unclear why the measure developer thought because some have succeeded despite this challenge that they should ignore the fact that the lack of health care infrastructure and other resources had presented a significant challenge to the hospital achieving a low level of readmissions. Failing to adjust for socioeconomic factors negates a very clear pattern of performance demonstrated not only by the data presented by the developer itself as shown above but confirmed by numerous studies now available in the literature and summarized in the AHA's *Trendwatch*, which is appended.

The developer also expressed some reluctance to adjust for socioeconomic factors under the mistaken belief that, by adjusting for them, the inference would be that it is accepable for poorer patients to have lower quality care. This argument is no more true than the argument that the age adjustment the developer has included in the measure is meant to suggest that it is permissible for older patients to receive poorer quality care than younger patients. The adjustment for age

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and for socioeconomic factors is simply meant to acknowledge that there are portions of the readmission puzzle that are outside the control of the hospital. They clearly contribute to the likelihood that a patient will be readmitted, yet are not a factor for which the hospital should be held responsible. By not adjusting for socioeconomic factors, the achievements of the high-performing hospitals serving impoverished communities will be undervalued.

The AHA and Association of American Medical Colleges (AAMC) recently contracted with KNG to further analyze patient characteristics that influence the proportion of patients who are readmitted. The KNG study used the proportion of dual eligible patients as a proxy for low socioeconomic status of the community; this proxy may be an even better measures of socioeconomic status when looking at readmissions for the Medicare patient population, as the CMS/Yale measure will likely do for the foreseeable future, since it specifically looks at the proportion of Medicare patients who are in poverty and eligible for Medicaid as well. The KNG data also show a clear relationship between low income and readmissions.

Readmission Rates are Higher for Dual Eligibles (2009)

30-Day Readmission Rates for Dual and Non-dual Eligible Beneficiaries



<u>Adequacy of the risk adjustment</u>. The AHA/ AAMC-commissioned analysis also shows a relationship between illness acuity and readmissions that extends beyond the current risk adjustment and raises questions about the adequacy of the risk adjustment used in the CMS/Yale measure. KNG noted a significant relationship between the number of previous admissions a patient had during the course of a year and the number of readmissions. The number of previous admissions within a year speaks clearly to the overall health of the individual, with those experiencing three or more admissions likely to be frailer or have more underlying health issues that make it challenging to keep the patient out of the hospital. Teaching hospitals and safety-net

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hospitals that specialize in caring for patients who are extremely complex and beyond the capacity of a typical community hospital are likely to be particularly disadvantaged by this insufficiency in the current risk adjustment methods. We urge the Steering Committee to task CMS to look carefully at how to use prior hospitalizations or improved clinical information to further risk adjust for the health status of patients.

Readmission Rates are Higher for Patients with Frequent Admits in Prior Year (2009)



30-Day Readmission Rates by Number of Prior-Year Hospital Admissions

Source: KNG Analysis of 2009 100% Medicare inpatient file and FY2011 Hospital IPPS final rule impact file.



Usability

We note that members of the Steering Committee gave both the CMS-Yale measure and the NCQA measure unusually low scores for usability, and we join with the Steering Committee members in noting that there are many, many challenges to using these measures to either inform the public or drive improvement. The consumer and purchaser representatives often comment that the existing condition-specific readmission measures create a large category of hospitals that are deemed to be no different in performance from the average, and hospitals find it confusing when they cannot replicate the readmission rate calculated for them. Many factors contribute to this inability to replicate the readmission rate. One of them is the same reason that makes it hard for consumers and purchasers to distinguish among hospitals, and that is the methodology essentially substitutes the national average for the hospital's own rate except to the extent there is enough data to allow one to say that the hospital's specific rate is different from the national norm in a statistically reliable way. This means that, for most hospitals, their readmission rate is not wholly their own, but is rather a blend of their own performance and the national average. For smaller hospitals, the calculated rate is predominantly the national average. As hospitals get larger, the rate becomes more their own and less of the national average.

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Additionally, as was noted in the Steering Committee meeting, these data are far from current. The data displayed on *Hospital Compare* for heart attack, heart failure and pneumonia readmissions at the moment are from July 2007 to June 2010, making the most recent data included in these calculations more than four and a half years to one and a half years old. As we understand it, the CMS/Yale readmission measure under review by this Steering Committee would likely only be displayed for a one-year period, not three like the current measures, which would mean the data at the time of display would be 18 to 30 months old. Data this old are challenging when one is trying to engage professionals in quality improvement efforts, tracking the changes one has put in place to see if they have had the desired effect or not, or trying to investigate any particular patient's case to see where there were opportunities for improvement.

We agree with the Steering Committee's votes indicating that the measures have, at best, limited usefulness in informing improvement or patient decision-making and would urge the committee to reconsider whether it is worth recommending a measure that it knows is not very useful.

In summary, we ask that the NQF reassess whether an expedited review was justified and, if it agrees that this project should not have been granted an expedited review, to take steps to minimize the impact that the expedited review had on the ability of the Steering Committee and interested stakeholders to participate in the project. Further, we ask that the Steering Committee reconsider the scientific acceptability of the measures and their usability and determine whether these measures are, in fact, worthy of NQF endorsement. If you have questions, please feel free to contact me at (202) 626-2337 or nfoster@aha.org.

Sincerely,

Nancy E. Foster Vice President, Quality & Patient Safety

Assessing Hospital Readmission Measures

Research Findings Study by KNG Health Consulting

Commissioned by the American Hospital Association and the American Association of Medical Colleges





Policy Background

- Affordable Care Act (ACA) includes Section 3025: Hospital Readmissions Reduction Program.
- Medicare payments for inpatient care will be reduced for hospitals with higher-than-expected readmission rates.
- CMS will use 30-day risk-adjusted all-cause readmission rates, as currently reported on Hospital Compare (www.hospitalcompare.hhs.gov).





Policy Background (Cont'd)

- Initially, payment reduction will be based on readmission rates for: heart attack, pneumonia and heart failure.
- Later, the list of conditions will expand as determined by the DHHS Secretary.
- CMS intends to use a regression-based risk standardization method that adjusts for age, sex and comorbidity and medical history.





Key Findings

 CMS' methods for risk-adjustment may not adequately adjust for factors beyond the control of hospital. In particular, the burden of the payment policy may fall mainly on hospitals and other facilities that treat the most vulnerable populations.





Study Question 1

How do readmission patterns vary by patient characteristics?





Readmission Rates are Higher for Non-whites (2009)

30-Day Readmission Rates for White and Non-white Beneficiaries







Readmission Rates are Higher for Dual Eligibles (2009)

30-Day Readmission Rates for Dual and Non-dual Eligible Beneficiaries

■ Dual Eligible ■ Non-Dual Eligible







Readmission Rates are Higher for Patients with Frequent Admits in Prior Year (2009)

30-Day Readmission Rates by Number of Prior-Year Hospital Admissions







Study Question 2

Does the CMS's risk-adjustment method (used for Hospital Compare) adequately adjust for factors beyond hospitals' control?





Approach: Data and Risk Adjustment

Category	CMS Model	Base Model	Alternative Model
Data Source	100% Medicare Inpatient Claims	100% Medicare Inpatient Claims	100% Medicare Inpatient Claims
Data Years	2007-2009	2009	2009
Risk Adjustment	 CMS-developed Co-morbidity Index 	 Elixhauser Co- morbidity Index 	 Elixhauser Co- morbidity Index
	Uses diagnosis information from claims for inpatient and outpatient services	 Uses secondary diagnosis from claim for index inpatient stay 	 Uses secondary diagnosis from claim for index inpatient stay
Control Variables	AgeGender	AgeGender	 Age Gender Other patient- specific factors



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Approach: Regression-Based Model

- Consistent with CMS, we used hierarchical linear model (HLM) to estimate the impact of factors on hospital readmissions.
- To assess adequacy of CMS model, we added variables in the HLM analysis:
 - Race (white or non-white)
 - Medicare/Medicaid dual status
 - Hospital supplemental security income (SSI) ratio
 - Whether a patient came from another acute care hospital
 - Number of hospital admissions in the previous year





Risk-Standardized Readmission Rate (RSRR): Heart Attack







Change in RSRR Under Alternative Model: Heart Attack







Risk-Standardized Readmission Rate (RSRR): Pneumonia







Change in RSRR Under Alternative Model: Pneumonia







Risk-Standardized Readmission Rate (RSRR): Heart Failure



Source: KNG Analysis of 2009 100% Medicare inpatient file and FY2011 Hospital IPPS final rule impact file.

American Hospital Association



Change in RSRR Under Alternative Model: Heart Failure



Source: KNG Analysis of 2009 100% Medicare inpatient file and FY2011 Hospital IPPS final rule impact file.

American Hospital Association



Study Implications and Policy Context

- CMS' methods for risk-adjustment may not adequately adjust for factors beyond the control of hospital.
- CMS argument for not controlling for patient socioeconomic factors: Need to address disparities; controlling for socio-economic factors gives hospitals a "pass."
- CMS argument is flawed: Leveling the playing field does not eliminate incentives in hospital readmission policy to reduce disparities.



