Helen Burstin, MD, MPH Senior Vice President for Performance Measures National Quality Forum 601 Thirteenth St, NW Suite 500 North Washington, DC 20005 Via e-mail:cardiovascular@qualityforum.org; hburstin@qualityforum.org

Dear Dr. Burstin:

Thank you for the opportunity to comment on the draft report of the National Quality Forum's Cardiovascular Consensus Standards Endorsement Maintenance project. On behalf of the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), and the American Medical Association-Convened Physician Consortium for Performance Improvement® (PCPITM), we support your overall efforts to expand the NQF portfolio and to ensure that only the best measures become NQF-endorsed voluntary consensus standards. Moreover, we recognize the challenges and opportunities the NQF Steering Committee (SC) faced in reviewing 57 cardiovascular measures across various conditions and care settings. We have reviewed the draft report and respectfully offer the following comments for your consideration.

We appreciate the SC's decision to recommend endorsement of the 2 atrial fibrillation measures (NQF #'s 1524, 1525), 3 heart failure (HF) measures (NQF #'s 0079, 0081, 0083), and 3 coronary artery disease (CAD) measures (NQF #'s 0066, 0067, 0074). Atrial fibrillation, HF, and CAD are major and growing public health problems in the United States. Atrial fibrillation is the most common arrhythmia in the United States, is a leading cause of stroke in the elderly, and is a life-complicating condition that reduces health-related quality of life and life expectancy. In 2010, it has been estimated that the prevalence of atrial fibrillation or atrial flutter ranges from 2.7 to 6.1 million people.^{1,2} Also, the costs to society will only increase with the expected growth in the prevalence, costs of cardiac ablation, and the advent of newer antiarrhythmic agents. HF is the leading cause of hospitalization and 30-day rehospitalization among patients enrolled in Medicare. Patients with HF have an estimated direct and indirect cost of \$37.2 billion and more Medicare costs are spent for the diagnosis and treatment of HF than for any other diagnosis.^{3,4} Coronary heart disease makes up more than half of all cardiovascular events in men and women less than 75 years of age.⁴ For patients with CAD, McGlynn et al. analyzed the quality of care in the United States and noted that these individuals receive the recommended quality of care only 68% of the time.⁵ With the formal endorsement from the NQF Board, this will strengthen our efforts to ensure the measures are more widely implemented in national programs that will enable us to test and refine these measures.

We strongly recommend the SC reconsider their decision to not recommend several of our measures as described below.

<u>Coronary Artery Disease and Heart Failure: Symptom and Activity Assessment Measures</u> (NQF #'s 0065, 0077)

The report indicates that the SC identified important gap areas for further measure development in cardiovascular care, namely "measures that assess functional status, stability, and symptom control based on patient reported data, particularly those that are likely to reduce emergency department (ED) visits and readmissions and improve quality of life." We agree that the portfolio of cardiovascular measures recommended for endorsement by the Steering Committee is notably missing measures addressing the assessment and management of patient-centric outcomes such as symptom and functional status.

For patients with CAD, those with frequent anginal symptoms experience lower quality of life,⁶ worse survival rates,⁷ higher costs,⁸ and more dissatisfaction with care than those with less severe symptoms.⁹⁻¹¹ Decreasing symptoms and improving function are therefore two of the primary goals of treatment for patients with CAD and HF.¹² The ACCF/AHA/PCPI Symptom and Activity Assessment measures for CAD and HF represent an important first step by focusing on the quantification of symptoms and activity with an emphasis on patients' perceptions of how their disease affects their daily functioning and quality of life. Data indicate that these assessments are not routinely conducted, even among the highly motivated clinicians participating in ACCF's PINNACLE registry.¹³ These data highlight a significant opportunity for improvement that would allow for additional measures promoting intensification of therapeutic interventions when symptoms are not adequately controlled.

While the landscape of performance measures is evolving and placing a greater emphasis on outcome measures, we believe that process measures remain critically important when addressing gaps in care and identifying opportunities for improvement particularly at the individual physician level, which is the primary focus of ACCF/AHA/PCPI measures. Patients' health status is a critically important outcome, and one that many patients value even more than the duration of their survival.^{14,15} Moreover, there is extensive documentation of racial disparities in coronary patients' health status,^{16,17} and the NQF has repeatedly emphasized its goals for reducing disparities. Additional NQF priorities to assess procedural appropriateness and to improve the efficiency of care are laudable goals for which the ACCF has developed Appropriate Use Criteria in the use of coronary revascularization, for which symptoms are *the* critical determinant.¹⁸ Thus quantifying patients' symptoms, function and quality of life is an essential process for using these as an outcome of clinical care and comparing quality across institutions and providers. We applaud the SC for recognizing the importance of clinical assessments (ie, left ventricular ejection fraction for HF, thromboembolic risk factors for atrial fibrillation) and would argue that assessment of a patient's symptoms and functional status are equally important in the management of patients with CAD and HF. Therefore, we strongly request that the SC reconsider their decision not to recommend these measures for endorsement.

We also request that the final report include the following correction. For the HF Symptom and Activity Assessment measure, the report incorrectly notes that testing results were not included with the submission. Over 10,000 patient records from the PINNACLE registry were analyzed to demonstrate performance rates and support the measure's reliability.

<u>Coronary Artery Disease and Hypertension: Blood Pressure Control Measures (NQF #'s</u> <u>1486, 0013)</u>

Several explicit principles have guided the development of performance measures by the ACCF, AHA, and PCPI over the past ten plus years of activity.¹⁹⁻²¹ One key tenet of this methodology requires that the measure be constructed so that the measure provides an accurate reflection of the quality of care provided – similar in concept to NQF's criterion of *Scientific Acceptability* which has been defined as the "extent to which the measure, as specified, produces consistent and credible results about the quality of care when implemented." Consistent with this methodology, the expert work group leading the development of the CAD and Hypertension measures developed the two Blood Pressure Control (now titled, Blood Pressure Management) measures to be met not only with achievement of the established BP goal but also with reasonable and evidence-based efforts to control BP.

By comparison, the Blood Pressure Management measures that the steering committee did recommend for endorsement are simple outcome measures with no risk adjustment that seek to identify the proportion of patients with ischemic vascular disease whose blood pressure was <140/90 mm Hg at their last visit (NQF #s 0076 and 0073). Recent research has highlighted the significant potential for misclassification with these types of measures - both at the level of the patient and at the level of the entity whose quality is being assessed.²²

Specifically, Powers and colleagues aimed to identify the optimal setting and number of blood pressure measurements that should be used for clinical decision making and quality reporting. The authors found significant differences in the proportion of patients who had controlled systolic blood pressure (SBP) in the first 30 days (<140 mm Hg for clinic or research measurement; <135 mm Hg for home measurement) by method of measurement -- 28% according to clinic measurement, 47% according to home measurement, and 68% according to research measurement. These findings are supported by another recent analysis which demonstrated that more than one third of the population of patients with resistant hypertension actually have white coat hypertension as detected by ambulatory BP monitoring.²³ Powers et al. concluded that more accurate classification of patients' BP control in a clinic setting could be achieved by using the average of several measurements and that a single measurement frequently misclassified a patient's level of control.²²

The ACCF/AHA/PCPI Blood Pressure Management measures emphasize the importance of the quality of the data used for clinical decision making. Recognizing that hypertension treatment decisions generally should be based on the average of multiple readings conducted in the clinician's office and the increasing role of blood pressure measurement outside the office (e.g., home and ambulatory blood pressure monitoring), the measure supports various more precise methods of BP measurement explicitly in numerator instructions and by requiring the provider to specify the BP reading that was used in clinical decision making.¹⁰

Persell et al. examined measures of hypertension quality first using simple measures [(ie, the proportion of diagnosed hypertension patients with their last BP below goal (<140/90 mm Hg or <130/80 if diabetic)] and compared these results to sequentially more complex measures. Baseline measures of control were 58.1% for nondiabetic patients and 29.9% for diabetic patients. Small modifications to measurement criteria resulted in significant increases in performance and offered a more accurate reflection of the proportion of patients receiving adequate care. For example, accounting for patients whose last or mean BP was at or below goal raised performance to 75.4% for nondiabetics and 46.4% for diabetics. Classifying patients prescribed aggressive treatment and with possible resistant hypertension as having adequate care raised performance to 82.5% for nondiabetics and 72.8% for diabetics. The results indicate that more complex hypertension measures may better identify patients with actionable uncontrolled BP, while not penalizing clinicians treating resistant hypertension patients which "could improve the detection of true quality problems and remove incentives to over treat or stop caring for patients with resistant hypertension."²⁴

Achievement of the ACCF/AHA/PCPI Blood Pressure Management measures requires that either the BP be < 140/90 mm Hg threshold or that 2 or more antihypertensive medications be prescribed for patients with BP \geq 140/90 in the absence of a medical-, patient-, or healthcare system-related reason that justifies not doing so. The work group recognizes that more than 2 BP lowering medications might be required to appropriately manage BP for some patients. However, the work group agreed that this consideration needed to be balanced against the more significant concern that promoting a strict standard would lead to adverse, unintended consequences related to overtreatment.¹⁰ The possibility for unintended consequences are further exacerbated by the fact that many patients with high BP or CAD have concomitant risk factors such as kidney disease, dyslipidemia, or diabetes.¹⁰ The other unintended consequence to consider is that an outcome measure based on a target level of BP may unfairly penalize providers who care for the sickest patients. The complex nature of BP control is addressed in the ACCF/AHA/PCPI measures, which incorporates many of the lessons learned by researchers in hypertension measurement and quality improvement. This approach has not only been demonstrated to provide a more accurate reflection of the quality of care provided, but it is also

more clinically credible and directly promotes the desired behaviors from clinicians managing the disease.

The Blood Pressure Treatment Trialists' Collaboration has reported results of prospectivelydesigned analyses of data from 29 randomized trials involving 162,341 participants with high blood pressure.

Participants' mean baseline blood pressure was 159/92 mm Hg, with mean values in the contributing trials ranging between 123 and 194 mm Hg systolic and 74 and 106 mm Hg diastolic. Treatment group differences in SBP averaged 5.4 to 8.4 mm Hg lower when active drug therapy was compared with placebo and 4.2 mm Hg lower when more intensive therapy was compared with less intensive therapy. In many of these studies, treatment regimens were compared, not different SBP or diastolic blood pressure treatment goals.

It follows logically that the mean on-treatment SBP in the more intensively treated groups has averaged over 150 mm Hg in the database that provides the evidence to support drug treatment of high BP. Lower levels of mean on-treatment SBP have been achieved in various individual trials, usually those with participants who started with lower baseline mean SBP. Those trials do not invalidate the conclusion that combination BP lowering drug therapy is very effective in reducing risk of heart disease and stroke in persons with high BP, regardless of the achieved on-treatment SBP. Physicians and patients who collaborate to follow a combination BP lowering treatment regimen are following good medical care. Whereas 3-drug therapy may be even more effective than a 2-drug regimen, the pertinent evidence base is limited. A 2-drug regimen is effective and evidence-based, and should be considered to represent adequate care for high BP. Moreover, Bakris et al., concluded that based on 6 out of 9 randomized clinical trials, the average number of BP lowering medicines needed to achieve target SBP was somewhere between 2 and 3 medications.^{25,26}

Our measures emphasize both the importance of monitoring BP and the care provided to patients with CAD and hypertension. Moreover, instead of simply recommending a 'plan of care', our updated BP measures require clinicians to actually control patients' BP. For all the reasons stated above, we recommend NQF reconsider their decision to not recommend measures 1486, 0013 for endorsement.

Coronary Artery Disease: Beta Blocker Therapy Measure (NQF #0070)

Based on the draft report, the National Committee for Quality Assurance's (NCQA) Beta Blocker measure (NQF #0071) was recommended over the ACCF/AHA/PCPI measure due to NCQA's focus on medication adherence rates. This NCQA measure—based on the Healthcare Effectiveness Data and Information Set—is attributable at the health plan, employer, and health system level. Although we agree that medication adherence is the desired outcome for patients and clinicians, the current state of data systems make this extremely difficult to implement at the individual physician level. At the individual level, prescribing clinicians do not usually have

access to pharmacy data or such data are prohibitively expensive to obtain. Furthermore, physicians care for members of multiple insurance plans and acquiring a comprehensive picture of individual physician performance using claims data would require combining the data from all of the plans which provide prescription coverage for the physician's patients. These sorts of data are currently not available for the vast majority of physicians. Another concern is that in the current health market, patients are also able to obtain inexpensive generic beta blockers from discount pharmacy programs that do not generate insurance claims. Therefore, a measure based on claims data alone will not accurately reflect whether patients are actually filling their prescriptions for beta blockers. We would also note that the ACCF/AHA/PCPI measure covers a broader patient population including patients with left ventricular systolic dysfunction in addition to those with prior MI. Additionally, by not relying on data generated through insurance claims, our measure may also be applicable to the more than 50 million Americans without health insurance.

We would also note that a number of factors that are beyond the control of the physician have a significant impact on medication adherence, including system-level factors such as health benefit design and copayment levels. Also, measures of adherence involve shared decision-making between patients and physicians. Based on patient autonomy, patients are free to decide whether to take medications prescribed to them. An unintended consequence may be that clinicians would avoid patients with a history of nonadherence.

Until newer methods of electronic transfer of information are available to track unfilled prescriptions, and until there is a restructuring of formularies and copayments as well as a system of shared accountability accounting for measurement of all individuals and entities, we believe it is inappropriate to make only the practicing clinician responsible for medication adherence rates.

The NQF Consensus Standards Approval Committee (CSAC) provided additional guidance to the Cardiovascular SC during phase 2 deliberations, indicating that, while electronic clinical sources should be preferred over measures that are primarily claims based, having only one measure for a condition may not be feasible at this time due to current limitations and transitions in data systems. Given the aforementioned challenges in collecting medication adherence data for physician level measurement, it appears this may be yet another instance in which data limitations necessitate the endorsement of 2 seemingly similar measures. *We would ask that the SC consider recommending both 0070 and 0071 for continued endorsement to be consistent with the CSAC guidance and their recommendations for other similar measures utilizing different data sources. We believe that the measures are complementary, not competing, given the different data sources and level of attribution.* Ultimately, by not recommending measure 0070, there will be no NQF-endorsed beta blocker measure for patients with CAD available at the individual physician level.

Outcome Measures Methodology

ACCF, AHA, and PCPI recognize the value of outcome measures to patients and purchasers. However, in comparison to structure and process measures, outcome measures are inherently more challenging to implement, especially if used to compare providers. Moreover, since this draft report has indicated that outcomes measures should have broad denominator populations, risk adjustment becomes even more critical to ensure the reliability and validity of the measures and to avoid unfairly penalizing providers who care for the sickest patients. We would recommend that NQF reaffirm in the final report that some type of risk adjustment should be employed for valid comparisons of outcomes measures across providers.

Related and Competing Measure Methodology

We appreciate the necessity for NQF to identify the "best in class" among competing measures, to move toward a more parsimonious measure portfolio (and prevent clinician fatigue), and to encourage harmonization whenever possible, as supported by our recent methodology paper on performance measurement.²¹ However, we continue to have significant concerns about the implementation of this policy. There may be valid scientific or practical reasons that developers have specified similar measures with slightly different denominators. It may be inappropriate to prefer measures that address the broadest possible patient population without full discussion of the evidence base supporting the difference and other considerations. The ACC/AHA/PCPI specifications were not arbitrarily chosen as the work group balanced these same issues during the measure specification progress. This approach seems inconsistent with NQF's own Evaluation Criteria for *Scientific Acceptability of Measure Properties*.

The jointly developed ACCF/AHA/PCPI measures that were submitted for NQF consideration have been well validated in a multi-disciplinary measure development process that has been refined and standardized over the past ten years.¹⁹⁻²¹ These measures were vetted by multiple stakeholders within various work groups. In addition to a 30-day public comment period and simultaneous expert peer review process, the measures were thoroughly reviewed and approved by ACCF/AHA Task Force on Performance Measures, the ACCF Board of Trustees, the AHA Science Advisory and Coordinating Committee, and the full PCPI membership.

We encourage NQF to carefully balance the necessity of having a more parsimonious measure portfolio with the necessity for keeping individual measures endorsed for the various reasons outlined in our comments above.

Composite Measures Methodology

As noted in the draft report, endorsing more composite measures would indeed reduce the necessity to harmonize individual measures. However, many of the individual measures are in wide use across various government programs and have also been retooled for EHRs. While composite measures—specifically those utilizing an all-or-none scoring approach—are

inherently appealing because they seem to provide an aggregate picture of performance, the construction of these measures can mask important and useful information if the individual components are not reported out separately. Determining the eligibility and exclusion criteria is also more challenging methodologically than the creation of individual measures. One gets the same credit for having achieved none of 6 measures in a composite as they would for achieving 5 of the 6 measures in a composite. The intention of our performance measure sets was not that medication alone should be used to improve patients' conditions. Rather, to manage patients' conditions, medications should be used in conjunction with other interventions such as weight loss, physical activity, and the promotion of dietary modifications.

We appreciate your time and consideration of the comments above and throughout the review process. We would be happy to discuss the issues further with you at any time.

Sincerely,

Jain Molme

David R. Holmes, Jr., MD, FACC President, American College of Cardiology

Gordon Tomaselli, MD, FAHA President, American Heart Association

Bernard Losof

Bernard M. Rosof, MD, MACP

Chair, Physician Consortium for Performance Improvement

cc: Robert O. Bonow, MD, MACC, FAHA, MACP Joseph Drozda Jr., MD, FACC Joseph V. Messer, MD, MACC, FAHA, FACP John Spertus, MD, MPH, FACC, FAHA N.A. Mark Estes III, MD, FACC, FAHA, FHRS Jonathan L. Halperin, MD, FACC, FAHA Eric D. Peterson, MD, MPH, FACC, FAHA Frederick A. Masoudi, MD, MSPH, FACC, FAHA Jack Lewin, MD, ACCF Staff Janet Wright, MD, FACC, ACCF Staff Charlene May, ACCF Staff Melanie Shahriary, RN, BSN, ACCF Staff Rose Marie Robertson, MD, FAHA, AHA Staff Gavle R. Whitman, PhD, RN, FAHA, FAAN, AHA Staff Mark D. Stewart, MPH, AHA Staff Jensen S. Chiu, MHA, ACCF/AHA Staff Karen Kmetik, PhD, AMA-PCPI Staff Mark Antman, DDS, MBA, AMA-PCPI Staff Greg Wozniak, PhD, AMA-PCPI Staff Samantha Tiernev, MPH, AMA-PCPI Staff Reva Winkler, MD, MPH, NQF Staff Kathryn Streeter, MS, NQF Staff

References

- 1. Go AS, Hylek EM, Phillips KA, et al. Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management and stroke prevention: the AnTicoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. JAMA. 2001;285:2370-5.
- 2. Miyasaka Y, Barnes ME, Gersh BJ, et al. Secular trends in incidence of atrial fibrillation in Olmsted County, Minnesota, 1980 to 2000, and implications on the projections for future prevalence. Circulation. 2006;114:119-25.
- 3. Jessup M, Abraham WT, Casey DE, et al. 2009 focused update: ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed

in collaboration with the International Society for Heart and Lung Transplantation. Circulation. 2009;119:1977-2016.

- 4. Lloyd-Jones D, Adams RJ, Brown TM, et al. Heart disease and stroke statistics-2010 update: a report from the American Heart Association. Circulation. 2010;121:e46-e215.
- 5. McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the United States. N Engl J Med. 2003;348:2635-45.
- 6. Spertus JA, Salisbury AC, Jones PG, et al. Predictors of quality-of-life benefit after percutaneous coronary intervention. Circulation. 2004;110:3789-94.
- 7. Spertus JA, Jones P, McDonell M, et al. Health status predicts long-term outcome in outpatients with coronary disease. Circulation. 2002;106:43-9.
- Arnold SV, Morrow DA, Lei Y, et al. Economic impact of angina after an acute coronary syndrome: insights from the MERLIN-TIMI 36 trial. Circ Cardiovasc Qual Outcomes. 2009;2:344-53.
- 9. Beinart SC, Sales AE, Spertus JA, et al. Impact of angina burden and other factors on treatment satisfaction after acute coronary syndromes. Am Heart J. 2003;146:646-52.
- Drozda J, Jr., Messer JV, Spertus J, et al. ACCF/AHA/AMA-PCPI 2011 Performance Measures for Adults With Coronary Artery Disease and Hypertension A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures and the American Medical Association-Physician Consortium for Performance Improvement. J Am Coll Cardiol. 2011;58:316-36.
- 11. Plomondon ME, Magid DJ, Masoudi FA, et al. Association between angina and treatment satisfaction after myocardial infarction. J Gen Intern Med. 2008;23:1-6.
- 12. Spertus JA. Evolving applications for patient-centered health status measures. Circulation. 2008;118:2103-10.
- 13. Chan PS, Oetgen WJ, Buchanan D, et al. Cardiac performance measure compliance in outpatients: the American College of Cardiology and National Cardiovascular Data Registry's PINNACLE (Practice Innovation And Clinical Excellence) program. J Am Coll Cardiol. 2010;56:8-14.
- 14. Lewis EF, Johnson PA, Johnson W, et al. Preferences for quality of life or survival expressed by patients with heart failure. J Heart Lung Transplant. 2001;20:1016-24.

- 15. Tsevat J, Dawson NV, Wu AW, et al. Health values of hospitalized patients 80 years or older. HELP Investigators. Hospitalized Elderly Longitudinal Project. JAMA. 1998;279:371-5.
- 16. Spertus J, Safley D, Garg M, et al. The influence of race on health status outcomes one year after an acute coronary syndrome. J Am Coll Cardiol. 2005;46:1838-44.
- 17. Spertus JA, Jones PG, Masoudi FA, et al. Factors associated with racial differences in myocardial infarction outcomes. Ann Intern Med. 2009;150:314-24.
- 18. Patel MR, Dehmer GJ, Hirshfeld JW, et al. ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization: a report by the American College of Cardiology Foundation Appropriateness Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, and the American Society of Nuclear Cardiology Endorsed by the American Society of Echocardiography, the Heart Failure Society of America, and the Society of Cardiovascular Computed Tomography. J Am Coll Cardiol. 2009;53:530-53.
- 19. PCPI Position Statement: The Evidence Base Required for Measure Development. American Medical Association. 2009. Available at: <u>http://www.ama-assn.org/ama1/pub/upload/mm/370/pcpi-evidence-based-statement.pdf</u>. Accessed August 2, 2010.
- 20. Spertus JA, Eagle KA, Krumholz HM, et al. American College of Cardiology and American Heart Association methodology for the selection and creation of performance measures for quantifying the quality of cardiovascular care. J Am Coll Cardiol. 2005;45:1147-56.
- 21. Spertus JA, Bonow RO, Chan P, et al. ACCF/AHA new insights into the methodology of performance measurement. J Am Coll Cardiol. 2010;56:1767-82.
- 22. Powers BJ, Olsen MK, Smith VA, et al. Measuring blood pressure for decision making and quality reporting: where and how many measures? Ann Intern Med. 2011;154:781-8.
- 23. de la Sierra A, Segura J, Banegas JR, et al. Clinical features of 8295 patients with resistant hypertension classified on the basis of ambulatory blood pressure monitoring. Hypertension. 2011;57:898-902.
- 24. Persell SD, Kho AN, Thompson JA, et al. Improving hypertension quality measurement using electronic health records. Med Care. 2009;47:388-94.

- 25. Bakris GL, Williams M, Dworkin L, et al. Preserving renal function in adults with hypertension and diabetes: a consensus approach. National Kidney Foundation Hypertension and Diabetes Executive Committees Working Group. Am J Kidney Dis. 2000;36:646-61.
- 26. Turnbull F. Effects of different blood-pressure-lowering regimens on major cardiovascular events: results of prospectively-designed overviews of randomised trials. Lancet. 2003;362:1527-35.