American Heart Association | American Stroke Association

May 7, 2012

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
P.O. Box 8013
Baltimore MD 21244–8013

Submitted electronically via www.regulations.gov

Re: CMS – 0044 – P

Dear Administrator Tavenner:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments to the Centers for Medicare and Medicaid Services (CMS) on the Electronic Health Record Incentive Program – Stage 2 notice of proposed rulemaking (NPRM).

Since 1924, AHA has dedicated itself to reducing disability and death from cardiovascular disease (CVD) and stroke—the #1 and #4 leading causes of death in the United States—through research, education, community based programs, and advocacy. To this end, the AHA is committed to improving the cardiovascular health of all Americans by 20 percent while reducing deaths from cardiovascular disease and stroke by 20 percent by the year 2020.

One of the AHA/ASA's approaches to achieving its mission is to continually raise the bar on quality patient care by advocating for, and creating systems, programs, and partnerships that ensure evidence-based medical guidelines are effectively translated into standard patient care. The flagship of these efforts is the Get With The Guidelines® (GWTG) suite of inpatient quality improvement programs which have impacted the care of almost 3 million patients and resulted in collation of over 4 million patient records in their supporting registries. The GWTG programs include in-hospital modules for myocardial infarction, heart failure, stroke, and resuscitation. In 2010, the AHA launched an outpatient program, The Guideline Advantage™ (TGA) that supports consistent use of evidence-based guidelines for prevention and disease management through existing health care technology.

Target: Stroke and Target: Heart Failure were developed as extensions of GWTG to further support the information translation and educational needs of healthcare providers caring for these patient populations, nationwide.

It is through the lens of these quality improvement programs and the health information technology tools that support their implementation and performance, as well as the needs of cardiovascular disease and stroke patients, that we submit the comments outlined below. We appreciate the opportunity to provide public comment on this proposed rule. Our comments fall into the following categories:

- Clinical Quality Measures
- Program Alignment
- Meaningful Use Objectives
- Interoperability
- Patient Engagement

Clinical Quality Measures

As a stakeholder actively involved in quality measure development, we recognize the importance of clinical quality measures and their ability to drive care improvements. We appreciate the inclusion of so many measures that address the care needs of cardiovascular and stroke patients. We encourage CMS to continue moving towards the inclusion of outcomes measures, particularly those that include patient reported outcomes, such as symptom management. We also encourage CMS to incorporate measures that more aggressively target disparities.

Our comments on the clinical quality measures proposed for inclusion in Stage 2 are limited to those related to cardiovascular disease and stroke, as well as the risk factors for these conditions. While we recognize it is not required by statute that measures included in the EHR Incentive Program be endorsed by the National Quality Forum (NQF), we encourage CMS to focus on those measures given the rigorous consensus development process they have gone through. In this way, we support the inclusion of the following NQF-endorsed measures:

- 0066 ACE Inhibitor or ARB Therapy
- 0067 Antiplatelet Therapy
- 0070 Beta-Blocker Therapy
- 0074 Lipid Control
- 0081 Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction
- 0083 Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction
- 1525 Atrial Fibrillation and Atrial Flutter

We would also suggest the inclusion of the following measures endorsed by NQF, but not included as proposed measures for Meaningful Use. These measures include:

- 1524 Assessment of Thromboembolic Risk Factors
- 0079 Left Ventricular Ejection Fraction (LVEF) Assessment

Additionally, we support the inclusion of 0028 Preventive Care and Screening: Tobacco Use and commend CMS for recognizing the need to address this important risk factor that is shared by many chronic conditions. We also support the inclusion of 0097 Medication Reconciliation for its potential to reduce complications and enhance the care of patients, such as those with complex cardiovascular conditions.

Program Alignment

We appreciate the efforts made by CMS to align measures across programs under its jurisdiction, as well as make the reporting mechanisms across these programs consistent in order to reduce provider reporting burden.

We would, however, encourage CMS to undertake this alignment more broadly and include private sector programs that share programmatic goals with the meaningful use program. For example, the American Heart Association/American Stroke Association's quality improvement program, Get With The Guidelines (GWTG), described above, uses a patient registry as the data collection tool for quality measure reporting and aggregates performance in order to benchmark participating hospitals. Using feedback reports that come from the program, hospitals and their providers work to improve healthcare quality. Additionally, program specific performance achievement awards are used to publicly recognize hospitals that meet each performance measure for a given condition in 85% or greater eligible hospitalizations for at least one year.

The GWTG program has demonstrated not only improvements in the reporting and achievement of quality measures, but improvements in health outcomes, as well. Among achievement hospitals, 30 day mortality was shown to be reduced for acute myocardial infarction and heart failure.[1] Additionally, stroke patients in enrolled hospitals showed reduced lengths of stay and improvements in risk adjusted in-hospital mortality rates.[2] Programs have also shown improvements in health equity with GWTG-CAD (now a joint program with the American College of Cardiology, called ACTION Registry-GWTG), reducing or eliminating healthcare disparities among patients in participating hospitals.[3]

We believe that the outcomes improvements that these programs have demonstrated are consistent with the end goals of the EHR Incentive program and should be aligned with and supported by meaningful use. This alignment could be achieved by creating proxies for Meaningful Use reporting using the existing reporting mechanism within these private sector programs.

[1] Am Heart J 2009;158:546-53.
[2] Fonarow GC et al. Characteristics, Performance Measures, and In-Hospital Outcomes of the First One Million Stroke and Transient Ischemic Attack Admissions in Get With The Guidelines-StrokeCirc Cardiovasc Qual Outcomes. Circ Cardiovasc Qual Outcomes. 2010;3:00-00.
[3] *Circulation*. 2010;121:2294-2301.

We believe this would also be consistent with a path considered by the HIT Policy Committee in their questions in preparation for their Stage 2 requirements. Under that line of inquiry, they asked responders to indicate whether high performance on quality measure reporting should be a substitute for demonstration of meaningful use. As we stated in our comments to the Policy Committee, given that Meaningful Use is intended to further the quality of patient care, we believe that hospitals and practitioners who are successful in demonstrating high performance on clinical quality measures and improvements in quality of care should be considered as meeting the Meaningful Use requirements. Further alignment between the EHR Incentive Program and existing private sector programs that have demonstrated care improvements would enable this to happen and further leverage existing efforts. In turn, this could also bring additional providers into the program who may have decided that the additional reporting burden of Meaningful Use did not provide sufficient benefit. This proposal is also consistent with a stated goal of CMS in regards to the structure of the Meaningful Use program, as stated in the NPRM, to look for ways to minimize provider burden.

We believe that once CMS examines the potential for using external programs as proxies for Meaningful Use reporting, they will find that there are several existing functionalities in currently available health IT tools which could further facilitate this alignment. Thresholds such as the designation of achievement by public recognition programs for quality improvement could also be used to identify the recipient as a meaningful user.

In this way, we encourage the Office of the National Coordinator for Health Information Technology (ONC) and CMS to further pursue ways to support the use of innovative private sector programs as proxies for participation in the EHR Incentive Program.

Meaningful Use Objectives

- **Clinical Decision Support**
  The AHA/ASA is generally supportive of the movement of most of the Meaningful Use objectives from the menu set in Stage 1 to core in Stage 2. In particular, we were very encouraged to see the clinical decision support objective measure moved to core.

- **Reporting to Cancer and Other Registries**
  Additionally, we were pleased to see the addition of the reporting to cancer and other registries as new menu objectives. We support these additions and agree with CMS that registries are an effective tool to promote both patient and population health. The inclusion of other registries will also promote the participation of specialty providers; we encourage CMS to work with these providers and registry developers to identify and approve the registries that best meet their needs and the needs of their patients. In this way, we encourage CMS to provide further information on what registries would be eligible and consider establishing baseline requirements for the registries to qualify in fulfilling this objective.

- **Advance Directives**

We were disappointed, however, to see that the advance directive menu objective was not moved to core as we recommended in our comments to the Policy Committee and the Policy Committee recommended to CMS. The AHA continues to support changing the advance directive objective from an optional objective to a requirement. Consistent with the overall patient and family engagement goal, a high quality health system is one that respects the values, beliefs, and wishes of the patient. Similarly, the meaningful use objectives are not only intended to spur the adoption of health IT, but also the use of that technology in a way that facilitates the delivery of high quality health care. An advance directive allows the patient to indicate his or her preferences about the care he or she receives at the end of life and serves as a surrogate for relaying that information when the individual is no longer able to communicate those preferences.

Additionally, randomized control trials have demonstrated the ability of advance directives to improve patient experience, by showing that their presence increases the likelihood that a patient's end of life preferences are known and respected and improves patient satisfaction and quality of life. Studies have also demonstrated that advance directives reduce the emotional trauma of the patient's family through reductions in post-traumatic stress, anxiety, and depression during the end-of-life and after the family member's death. [4]

- **Inclusion of Physical Activity Assessment**
  In addition to the modifications suggested above, we also recommend the addition of two physical assessment questions into Stage 2 of the Meaningful Use program. Given the speed with which these questions can be recorded and the limited burden associated with recording the answers to these questions, we believe they should be considered part of the vital sign metric. The specific questions that we recommend be used are the "Electronic Vital Signs (EVSs)" piloted by Kaiser Permanente and that received consensus support at the recent American College of Sports Medicine (ACSM) conference. The questions are:
  1. How many days of moderate to strenuous exercise, like a brisk walk, did you do in the last 7 days?
  2. On those days that you engage in moderate to strenuous exercise, how many minutes, on average, do you exercise at this level?

  As exercise and physical activity are integral to the prevention and treatment of chronic disease, they should be regularly assessed as part of medical care. Physical *in*activity, one of the leading modifiable risk factors for death in the U.S., however, has no regular assessment or intervention conducted in primary care. Kaiser Permanente has developed an assessment and has successfully incorporated two evaluative questions into an electronic platform that it piloted with physicians. Questions were designed and revised in order to align with the ways that patients think about physical activity.

[4] Detering KM, et al. "The impact of advance care planning on end of life are in elderly patients: randomized controlled trial'. *British Medical Journal* 2010; 340:c1345.

Additionally, to address the critical need for patient-reported data, several institutes/offices from the National Institutes of Health, in collaboration with the Society for Behavioral Medicine, coordinated an effort to evaluate and recommend common data elements (CDEs) for patient-reported measures of health behaviors and psychosocial factors for use in electronic health records. At this meeting, the two questions above were vetted by ACSM and consensus was developed around the use of these specific questions as industry standard.

Incorporating these questions would also be technologically feasible. ACSM has had preliminary conversations with vendors about the integration of these questions into their electronic health record platform and vendors have stated that incorporating these questions would be "comparatively easy and inexpensive" since it only requires the addition of fields and no coding changes.

Kaiser's experience also demonstrates the integrating these questions into regular patient care is easy and has minimal burden to providers and the overall delivery of patient care. According to Kaiser's survey of physicians using the questions: a majority (85%) found the questions easy to use and 78% did not believe it to be time consuming; it took an average of 2.5 minutes per patient to conduct the assessment; 67% stated that the questions have made them more likely to discuss exercise with patients; and 65% of physicians feel more confident having this discussion with patients when using the questions.

Regarding the specifics of the questions, clinicians could use the "sing-talk test"[5] to help patients define the terms "moderate" and "vigorous" exercise as used in the questions. Minute increments would be used as the unit for this question to align with physical activity guidelines which are given in minutes. The target demographic for the EVS is all patients 18 and older. Electronic records, however, could include a medical exclusions text field and/or options for possible exclusions. The exercise vital sign would be composed of the two questions above, with one flag/prompt to alert physicians of those patients not reaching the recommended 150 minutes per week.

Adding these questions to Stage 2 would give providers important information related to a patient's exercise habits and put a patient's exercise history into a uniform format that a patient would be able to take with him/her when they transfer physician offices. In this way, it aligns with the information portability and patient empowerment goals of Meaningful Use for Stages 2 and 3. Additionally, the new physician/practice would also receive information as to how the patient was doing in his/her last recorded visit as compared to the patient's current presentation. In this way, the patient's improved, maintained, or worsened physical activity status could be tracked and known to the new physician. This information would support the type of care recommendation and counseling that the new physician may give to a patient and support overall care coordination efforts.

[5] Using this test, "moderate" is defined as working hard enough to be able to carry on a conversation, but not be able to sing. "Vigorous" is defined as working so hard through exercise that the patient cannot carry on a conversation.

The premise on which these questions are based also has sound scientific evidence. In addition to improving a patient's overall health, increasing physical activity has proven effective in the treatment and prevention of chronic diseases. More specifically, research demonstrates that physical activity can have the following positive benefits for individuals with chronic diseases when conducted at the correct intensity: reduces the risk of heart disease by 40%[6]; lowers the risk of stroke by 27%[7]; reduces the incidence of diabetes by almost 50%[8]; and reduces the incidence of high blood pressure by almost 50%[9].

Research also demonstrates the impact of physical *in*activity. A low level of cardio respiratory fitness (CRF) exposes a patient to a greater risk of dying than does smoking, obesity, hypertension, or high cholesterol.[10]

We advocate for the inclusion of physical exercise as part of the vital sign metric, as soon as possible, although understand there may be questions from ONC that may make it more appropriate for inclusion as part of Stage 3. AHA/ASA staff, as well as ACSM staff would be happy to speak with staff at ONC and CMS about these questions and help answer any questions they may have. We look forward to working with the Administration to get this very important element of health incorporated into the regular medical visit.

Interoperability

Health IT and the interoperability it can enable is essential to improving the quality of healthcare and the performance of the larger healthcare system, as well as reducing the cost of care; we believe ACOs, medical homes, hospital readmission programs, and other delivery mechanisms cannot be implemented well without strong standards for interoperability. The increased emphasis on interoperability In Stage 2 represents a significant step forward from Stage 1. And while we commend the move of the test of data exchange in Stage 1 to the actual exchange of a summary of care record from one provider to another as part of Stage 2, it does not go far enough to support the type of robust interoperability required to reap the full benefits of health IT implementation.

The Direct project is positive for several reasons, including its ability to be rapidly implemented and send discrete pieces of information. The reliance on the ability to "push" information to other providers, however, does not incent those other providers to have the capabilities to receive data from the individuals pushing the information, nor does it encourage those pushing the information to receive updated or additional data to the original sent data. Additionally, as stated earlier, while rapidly implementable and good at sending discrete information, Direct is not good at aggregating information to assist the delivery of care in coordinated settings. It is critical, however, for new and emerging delivery models, such as ACOs, that all information on a patient is known in developing revisions to a care treatment plan. Certain medication reconciliation scenarios could be satisfied by

[6] Med Sci Sports Exerc. 1994 Jul;26(7):807-14
[7] AMA. 2000 Jun 14;283(22):2961-7.
[8] Wei M et al. *Annals of Internal Medicine.* 1999
[9] Barlow CE et al. *Am J Epidemiol* 2006; 163:142-50
[10] Blair SN. Physical inactivity: the biggest public health problem of the 21st century. *Br J Sports Med* 2009; 43:1-2

Direct services (i.e., those where the relevant providers are actively sending the patient to a new setting), but trying to retrieve a patient's medication history from all the providers in a community would not be supported easily. In this way, we believe that adopting Direct as an exclusive requirement for purposes of the NPRM works against shared goals in lowering costs and improving quality through more robust transport standards.

Patient engagement

The AHA/ASA supports the trend toward greater engagement of patients and their caregivers in the proposed rule. Proposed requirements that encourage increased patient electronic access to their health information, health education resources, and communication with their caregivers will support the ability of patients to be active and engaged participants in their healthcare. Additionally, greater engagement of patients in Stage 2 is necessary preparation for the heightened levels of patient participation anticipated in future stages of the EHR Incentive program, and will support a safer, more open, and efficient system in the future.

We believe that key aspects of patient engagement will only be fostered through true interoperability that supports the sending and receiving of information. This is particularly important especially for those with chronic illnesses and multiple conditions.

Thank you very much for the opportunity to provide comment on the EHR Incentive program. We look forward to working with the Administration to make this program as effective for and beneficial to the healthcare system, as possible.

Sincerely,

Gordon F. Tomaselli, MD, FAHA
President, American Heart Association