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November 12, 2013

The Honorable Max Baucus
Chairman
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Orrin Hatch
Ranking Member
Committee on Finance
219 Cannon House Office Building
Washington, DC 20510

The Honorable Dave Camp
Chairman
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
1106 Longworth House Office Building
Washington, DC 20515

Dear Senators Baucus and Hatch and Representatives Camp and Levin:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to provide comments on the Committees' SGR Replacement Framework. With our own impact goal to improve the cardiovascular health of all Americans by 20% by 2020, the American Heart Association/American Stroke Association (AHA/ASA) is acutely aware of the need for systematic reform to improve the quality of healthcare in this country. In this way, the AHA/ASA is very pleased with the combined efforts of the members of the Senate Finance and House Ways and Means Committees to come together on a bipartisan proposal to address longstanding issues with the physician payment formula. We genuinely believe that if, as hoped, this latest legislative effort produces a permanent fix to the SGR that promotes the delivery of high quality health care, patients will be the real winners.

Benefits and Goals of Payment Reform

For over a decade, the AHA/ASA has dedicated significant effort and resources to quality improvement on behalf of the nation's heart and stroke patients. The prospect of the broader inclusion of these initiatives within the Medicare program is gratifying and a positive step toward providing all Americans with the quality health care they so deserve. Through this experience, we have identified several elements that are critical to successful and sustained quality improvement - the development of and adherence to clinical practice guidelines and measures; the use of clinical data registries; robust data linkage; hands-on support/technical assistance; and seamless care coordination across the care continuum. We believe that these are not only the critical elements of quality improvement; they are also the necessary components for an equitable value driven payment model. It is imperative, however, that this framework doesn't lose site of the overall goal for a reformed system – one that is based on tested and proven models, supportive of the best clinical evidence, and truly patient-centered.

We have had a chance to review the framework in more detail and are overall supportive of it, believing that it contains several of the important components listed above. Below we provide support and reinforcement for their lasting inclusion in the framework as it moves forward. There are, however, a few areas that cause concern for their potential to steer the system away a truly evidence-based one and generate unintended consequences; we have taken this opportunity to highlight those and provide suggestions for ways in which they may be adjusted.

Value-Based Performance (VBP) Payment Program - Quality Measures Assessment Category

The AHA/ASA, on its own, and in partnership with other organizations has spent considerable effort on the development of evidence-based clinical practice guidelines, which have then informed the development of performance measures for physicians. We know first-hand the high cost and resource intensive nature of the performance measure development and endorsement process and appreciate the availability for funds for organizations, such as ours, to do this work. We would also like to point out that in addition to the importance of funding to support expanding measure development, attention still needs to be paid to the existence of a neutral endorsement body to ensure a high-bar for the evidence requirements and consensus in support of a particular measure. Additionally, is important that stakeholders with expertise in the particular disease states have measurable input into program design and implementation of the new VBP, particularly when determining the measures for inclusion in the program. Groups like the AHA/ASA and professional societies, as well, have significant experience in translating evidence into guidelines and performance measures. Representatives from these groups must be at the table as the details for a program that links payment to quality are determined and rolled out.

While we understand the Committees' desire to measure the ultimate goal of the healthcare system – improved patient outcomes– we strongly caution against moving too quickly for fear of adopting measures that may actually harm patient care by misrepresenting care that is delivered. The framework calls for a higher overall weight to be given to outcomes measures but we would like to point out that there are substantial limitations to many of the existing outcomes measures. The covariates are complex and as a result, performing well on a particular outcome does not always equate to the delivery of high quality care. Conversely, performing poorly on a particular outcome measure does not necessarily indicate the provision of poor quality. In this way, we believe that not only should money be available for new measure development, but that this funding should also be used to rigorously, prospectively test outcomes measures to ensure that they are truly driving towards better quality. While this testing is being conducted, the program should rely only on tested and validated process measures that are based on evidence-based care guidelines and have been tied to demonstrable impacts on care quality. Outcomes measures can then be phased into the program as they are tested and found to *accurately* measure quality.

When outcomes measures are eventually incorporated, it is imperative that they be appropriately risk adjusted with factors that relate to patient variables. All risk-adjustment is not of equal rigor and we caution against the use of factors that do not reflect patient variables in order to create the appearance of risk adjustment. In the absence of adequate risk adjustment, these measures will be poor proxies for quality.

Value-Based Performance (VBP) Payment Program - Use of Clinical Data Registries

In the AHA/ASA's experience in quality improvement, clinical data registries, such as the Get With The Guidelines (GWTG) Program, have been demonstrated to identify and close gaps in quality of care by supporting effective, continuous quality improvement processes.ⁱ By capturing and aggregating clinical information throughout the course of care, registries enable the use of performance measures to accurately measure patient outcomes and clinical practice and feed

information back into the system to create a true learning healthcare system. For this reason, we are very pleased to see the inclusion of clinical registries as both a data aggregation and reporting mechanism, as well as a way to report feedback to providers and infuse data into the healthcare system. We would like to point out, however, that the descriptor of “specialty society” is used several times in the framework. We wish to emphasize that there are voluntary health organizations such as the AHA/ASA, with a broad mission to improve the health of the population, that have dedicated significant resources to developing quality improvement programs using clinical registries in the ways that the Committee envisions their supporting the VBP program. We hope the Committees will revise the language so it is clear that the registries included are not limited only to those of specialty societies.

Similarly, we would like to clarify that a registry can be a reporting option under the combined VBP. They are referenced as a group reporting option, but for individual practitioners (or at least how it appears in the framework as currently written) that only EHRs can be used for this function. If our reading was the intention of the Committees, we encourage you to include registries in subsequent revisions.

Additionally, no definition is provided in the framework for the term “qualified clinical data registry.” We believe you may be referring to the new reporting option introduced in last Physician Fee Schedule. In our comments on that rule, we included a set of clarifying questions, which we encourage you to review. One of our points is particularly relevant to this framework. According to the proposed rule qualified registries are to “provide timely feedback at least quarterly so eligible professionals could view their reporting at least 4 times during the yearly reporting period.” Certain registries such as those that support the AHA/ASA’s GWTG quality improvement program have the ability to allow users to generate reports on an “on demand” basis. We would encourage you to consider the criteria for more regular feedback than quarterly and potentially require the ability for registry users to be able to run standard reports on demand.

Value-Based Performance (VBP) Payment Program - Assistance to Small Practices

We support the inclusion of money to support QIOs in helping small, HPSA/rural practices in developing alternative payment models. We know firsthand from our work implementing GWTG in the hospital setting, as well as The Guideline Advantage in outpatient practices, the importance of and need for hands-on technical assistance in implementing systems changes. The support provided by this funding will be critical to the ability of these practices to implement lasting and successful changes.

Encouraging Care Coordination for Individuals with Complex Chronic Care Needs

We support the framework’s establishment of payment for one or more codes for complex chronic care management services. Our patients are very aware of the importance of care coordination in effectively managing their chronic conditions. Incentives must be in place to support the delivery of services across care settings and between providers. We understand the logistical need to avoid duplicative payment for these services. We are concerned, however, about the proposal to only pay one of the many providers included as part of the care coordination team. This puts the onus on that single provider to establish the mechanisms to pay the other members of that team. If this process becomes too cumbersome for any member of that team or results in a delay in payment, it could serve as a disincentive for providers to engage in these services with other providers and perpetuate the care silos these codes are attempting to break down.

Recognizing Appropriate Use Criteria

We caution that a system as large in scope and significance as the one the Committees are attempting to create through this framework has the potential to create perverse incentives for the

providers who participate in it and detrimentally impact the quality of patient care. We believe that a system such as the committees are trying to lay out must be based on the most rigorous scientific evidence developed through unconflicted processes.

We enthusiastically support the proposal's attempt to improve the value of advanced imaging and echocardiogram services by eliminating overuse. However, we would like to raise serious concerns about whether the framework specific language on AUCs will achieve this goal. The ability of clinical decision support tools in general, and those incorporating AUCs in particular, to alter professional behavior in non-cardiologists has not been consistently demonstrated. Within the past few years, the language associated with the categories in the cardiovascular disease AUCs has been modified to "appropriate", "may be appropriate", and "rarely appropriate" to support more professional flexibility. A recent study of 11 outpatient community-based practices in the Chicago metropolitan area reported an overall rate of "rarely appropriate" nuclear cardiology studies of 45%, with rates of "rarely appropriate" studies as high as 77% in individual physicians. We would respectfully suggest that Congress cannot assume that "consultation" with AUC by such professionals will alter their behavior until it has been proven to do to.

We would also strongly suggest that clinical practice guidelines are a better tool to achieve this goal than AUCs. In the Medicare Improvements for Patients and Providers Act of 2008, Congress directed the Institute of Medicine to develop standards for clinical practice guidelines, which led to the publication of the report entitled "Clinical Practice Guidelines We Can Trust" by the IOM in 2012. The American Heart Association has 29 years of experience in the development of clinical practice guidelines, which is detailed on page 40 of the IOM report. Although AUCs are commonly referred to as "guidelines", they do not meet the standards outlined in the IOM report, particularly for evidence foundations for (standard #5), or articulation of (standard #6), recommendations. The fundamental differences between clinical practice guidelines and AUC are further detailed in a widely cited article entitled "Tools for Guiding Clinic Practice in the American Heart Association and American College of Cardiology: What Are They and How Should Clinicians Use Them?"ⁱⁱ We would suggest that clinical practice guidelines that meet the standards outlined in the IOM report are the best evidence-based tool to achieve the quality improvement sought by this proposal.

Expanding the Use of Medicare Data for Performance Improvement

As a recent report in the AHA's journal *Circulation* points out, "by linking hospitalization records from Medicare claims with Get With The Guidelines clinical registries, an inpatient episode with longitudinal follow-up can be used to conduct CER."ⁱⁱⁱ The paper goes on to point out several examples of ways in which this linkage has identified gaps in care and adjusted practice patterns to address it and acted as a surveillance network to evaluate the effectiveness of cardiovascular therapies in the real-world. In this way, we support the framework's increased access to administrative data by expanding the definition of qualified entity, as well as the types of data which would be available. As we noted above, however, it is imperative that these data be timely in their release. Registries are able to provide real-time information and if the lag for administrative data is too far behind the clinical data, access to that data is useless.

Transparency of Physician Medicare Data

AHA understands the desire to provide meaningful information to beneficiaries to empower and support them in making decisions about their healthcare providers. We are very concerned, however, about the proposal to post physician-level "utilization and payment" data on the Physician Compare web site. First, we believe that the Committees need to provide more information as to what types of information they have in mind. Regardless, however, if this type of information is not adequately risk adjusted and if beneficiaries do not understand what the data truly represent, there is the potential it will be significantly misleading to beneficiaries who are trying to inform their

healthcare decisions. Additionally, it could be detrimental to patient care in areas where there are large numbers of patients with low socio-economic status and low literacy rates. Providers would have an incentive to turn away patients with low health literacy, inadequate financial resources to afford treatment, and ethnic groups traditionally subject to healthcare inequities in order to improve the data posted about them. In this way, the risk that providers would deselect high risk populations to maintain high scores on publicly reported websites is high.

Before a program such as this is broadly implemented, therefore, we strongly encourage the Committees to make efforts to better understand how information is perceived by the public and how it is used. If it is determined that there is a low level of understanding or misunderstanding about the data, we believe that this does not justify the continued posting of such information moving forward and this component of the proposal should be reevaluated.

Thank you for the opportunity to comment on this important framework. We would be happy to talk with you more about our comments, as well as put you in touch with our volunteer experts who can speak about their experiences in quality improvement and clinical practice guidelines and performance measure development. Please do not hesitate to contact our Washington, DC based staff, Madeleine Konig, Senior Policy Analyst, at madeleine.konig@heart.org or Marko Mijic, Government Relations Manager, at marko.mijic@heart.org.

Sincerely,



Mark A. Schoeberl
Executive Vice President
Advocacy & Health Quality

ⁱ Ellrodt, AG, et al. "Synthesizing Lessons Learned From Get With The Guidelines: The Value of Disease-Based Registries in Improving Quality and Outcomes." *Circulation* 2013.

10.1161/01.cir.0000435779.48007.5c.

ⁱⁱ *Circulation* 2009;199:1180-1185.