Heart Disease and Stroke. You're the Cure.

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September 16, 2010

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
Attention: RIN 1210-AB44

Office of Consumer Information and Insurance Oversight
U.S. Department of Health and Human Services
Attention: OCIIO-9992-IFC

Internal Revenue Service
U.S. Department of the Treasury
Attention: REG-120391-10

**Re: Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act**

Dear Sir/Madam:

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 comment on the "Interim Final Rule for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act (ACA)."

Since 1924, AHA has dedicated itself to reducing disability and death from cardiovascular disease and stroke—the first and third leading causes of death in the United States—through research, education, community-based programs and advocacy.

AHA/ASA's Commitment to Prevention

For more than fifty years, AHA/ASA has developed and published scientific resources – including scientific statements, clinical practice guidelines, science advisories and performance measures – to improve the prevention and treatment of cardiovascular disease and stroke. Our peer-reviewed, evidenced-based scientific guidelines are an important resource used by clinicians, public health leaders and policy makers, to design and implement clinical and community-based prevention services and interventions.

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Examples of these tools include the following:

- American Heart Association, *Guidelines for Primary Prevention of Cardiovascular Disease and Stroke*
- American Heart Association, *Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women: 2007 Update*
- *American Heart Association/ American College of Cardiology Found*ation, *2009 Performance Measures for Primary Prevention of Cardiovascular Disease in Adults*
- *American Heart Associ*ation, *Population-Based Prevention of Obesity: The Need for Comprehensive Promotion of Healthful Eating, Physical Activity, and Energy Balance*
- American Heart Association/American College of Cardiology, *Guidelines for Secondary Prevention for Patients With Coronary and Other Atherosclerotic Vascular Disease*
- American Heart Association, *Guidelines for Primary Prevention of Atherosclerotic Cardiovascular Disease Beginning in Childhood*
- American Heart Association/American Stroke Association, *Guidelines for Prevention of Stroke in Patients With Ischemic Stroke or Transient Ischemic Attack*
- American Heart Association, *Diet and Lifestyle Recommendations*; and
- American Heart Association, *Guide for Improving Cardiovascular Health at the Community Level.*

Over the past 60 years, we have also invested more than $3.2 billion in building the clinical research base to improve the prevention and treatment of heart disease and stroke. Our volunteers work in communities across America to promote healthy lifestyles and reduce cardiovascular disease and stroke risk.

Given these efforts, we have long known that affordable access to preventive services is vital to ensuring that risk factors are identified early and effective strategies are implemented to prevent heart disease and stroke. It is for this reason that AHA/ASA was an early voice calling for Medicare coverage of preventive services. At the start of this decade, AHA/ASA led the successful campaign to add cardiovascular screening blood tests as a Medicare benefit. We also supported waiving coinsurance and deductibles for screening-related clinical laboratory tests and were instrumental in the development of the initial preventive physical examination or Welcome to Medicare Visit. More recently, we advocated successfully for the creation of a new annual wellness visit for Medicare beneficiaries, established in the Patient Protection and Affordable Care Act.

The AHA/ASA also helped lead the effort to give the Secretary of Health and Human Services the authority to make determinations regarding the coverage of new preventive benefits in Medicare based upon the “A” and “B” recommendations of the United States Preventive Services Task Force (USPSTF) in the Medicare Improvements for Patients and Provider Act. The ACA takes the next important step in improving access to preventive services by addressing the affordability of preventive services recommended with an “A” or “B” by the USPSTF.

The policy changes made in ACA to advance preventive care are essential to the AHA/ASA mission of building healthier lives, free of cardiovascular diseases and stroke. AHA/ASA strongly supports ACA's provisions focused on removing cost-sharing barriers to preventive services.

In large part, the AHA/ASA supports much of this interim final rule on preventive services and applauds the Secretaries for their leadership in this area. Importantly, this interim final rule provides guidance around the ACA provision that requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide benefits with no additional cost-sharing for certain preventive services as defined in the ACA. While the AHA/ASA supports the content of much of this interim final rule, there are a number of areas in which we suggest refinements or additional guidance including:

1. Reasonable Medical Management Techniques
2. Screening for High Risk Individuals
3. Value-based Insurance Design
4. Primary Purpose Test
5. United States Preventive Services Task Force's Structure and Processes
6. Reviewing and Updating Preventive Services

**1. <u>Reasonable Medical Management Techniques</u>**

The interim final rule provides that if a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer can use "reasonable medical management techniques" to determine any coverage limitations. The interim final rule explains that a plan or issuer should rely on established techniques and the relevant evidence base to determine the frequency, method, treatment, or setting for which a recommended preventive service will be available, without cost-sharing requirements, to the extent it is not specified in a recommendation or guideline.

The AHA/ASA urges the Secretaries to refine this guidance in the following ways:

- ***Define reasonable medical management techniques***:

  As currently stated, the interim final rule would allow plans or issuers great discretion regarding the frequency, method, treatment or setting for the provision of specific recommended preventive services. This broad discretion could result in dramatic differences in how and when patients receive these services. The intent of ACA is to create a preventive benefit standard to ensure that Americans have equal access to vital, scientifically recommended prevention services. Allowing for variation in these services at the discretion of the plan or issuer undermines this intent. For example, a USPTF recommendation might call for "diet counseling" but might be silent regarding the form or frequency. In this example, plans could choose the least expensive and least effective means of counseling (i.e., cover recorded telephone messages only versus face-to-face sessions.)

  The final rule should not leave the key issues of implementing preventive services to the plan or issuer. In fact, in operationalizing USPSTF recommended services, the Centers for Medicare and Medicaid Services (CMS) regularly specifies the scope and frequency of the benefit to be covered. Additional guidance is needed to better document expectations in this area. Working with various stakeholders including the AHA, we urge CMS to set some standards in circumstances where the recommendations are not clear and not leave these standards to individual plan or issuer interpretation. At a minimum, the rule should clearly define "reasonable medical management techniques" and require that the frequency, method, treatment

or setting regarding preventive services be no less than what Medicare requires when it provides coverage for a recommended preventive service.

- ***Clarify credible sources:***

  The final rule should clarify what sources of credible evidence plans and issuers should rely upon to support the delivery of preventive services and reasonable medical management techniques. The final rule should provide specific examples of acceptable and unacceptable sources. For example, plans and issuers should be encouraged to use nationally recognized evidence-based guidelines such as the AHA/ASA recommendations on preventive care related to cardiovascular disease and stroke.

- ***Define "services not recommended":***

  For services "not recommended" by the USPSTF, the statute provides, and the regulations reflect, that plans are allowed to deny coverage for services that are "not recommended" by the Task Force. The rule should explicitly clarify that services "not recommended" by USPSTF are those services receiving a grade of "D" from the Task Force. This clarification is necessary to ensure that plans do not deny coverage for beneficial screenings that are simply not addressed by the USPSTF. Only services receiving a grade D, by definition, are not recommended by the Task Force. This clarification will help to minimize denial of coverage for certain preventive services that may not yet be addressed by the USPSTF.

- ***Out of network providers:***

  The interim final rule explains that screenings/services provided by out-of-network providers are subject to cost-sharing. The final rule should clarify that cost-sharing for out-of-network providers should not be any higher than cost-sharing for other ambulatory health care services provided out-of-network.

- ***Appeals:***

  The Secretaries should inform consumers about the new preventive services coverage and cost-sharing requirements of ACA in plain language. Culturally sensitive materials need to be used in order to appropriately and effectively communicate to all risk groups. Clear information should be provided annually to consumers about their rights to appeal any plan or issuer determination that is inconsistent with the requirements of ACA and about the processes to appeal determinations. The Department of Health and Human Services and the Department of Labor should initiate oversight strategies to monitor compliance with the preventive benefit requirements of ACA and to determine whether consumers are receiving appropriate preventive benefits without cost-sharing.

## 2. Screenings for High-Risk Individuals

Some USPSTF recommendations address screening for high-risk populations, while others do not. For individuals with chronic conditions who are at higher risk for certain preventable conditions, additional screenings are crucial. For example, for individuals at risk for cardiovascular disease and stroke, lipid screening may be required more frequently.
In instances where the USPSTF recommendation is not clear regarding screening of a high-risk patient, the physician's clinical judgment should dictate the frequency of screenings. In these instances, no cost-

sharing should apply. Some flexibility needs to be allowed to account for the individual patient variability in responsiveness to measures to control various risk factors.

**3. Value-based Insurance Design**

Value-based insurance design can minimize or eliminate out-of-pocket costs for high-value services provided to a defined patient population. The interim final rule allows value-based insurance design by permitting plans and issuers to "implement designs that seek to foster better quality and efficiency by allowing cost-sharing for recommended preventive services delivered on an out-of-network basis while eliminating cost sharing for recommended preventive health services delivered on an in-network basis."

The Departments are developing additional guidance regarding the utilization of value-based insurance design by group health plans and health insurance issuers with respect to preventive benefits. The interim final rule requests comments related to the development of these guidelines that would "promote consumer choice of providers or services that offer the best value and quality, while ensuring access to critical, evidence-based preventive services."

In general, the AHA/ASA supports research and testing of value-based insurance design concepts. Reducing the cost of co-pays for chronic illness treatments improves medication compliance and may significantly impact long-term costs of treating chronic diseases. For example, value-based insurance design might suggest that certain drugs used to treat conditions such as heart disease, hypertension, or diabetes should have lower cost-sharing than medications that treat non-life threatening conditions. If people do not have a barrier—such as cost—to accessing necessary drugs, they are more likely to use them.

Although AHA/ASA supports the concept generally, it is our understanding that some policy leaders have suggested that the value-based insurance design model allow for a voucher-type program in place of insurance coverage and that instructions would be provided to an individual to "shop for the best deal." This is not value-based insurance design, and the final rule should prohibit it. Instead, the definition of value-based insurance should be clearly stated in the final regulation consistent with the intent in ACA. Regulations defining value based insurance design should make it clear that the program must be aimed at improving health outcomes and increasing quality of care. A program that aims to reduce costs by limiting services or access is not a value-based program and will not achieve the preventive services intended under ACA.

Value-Based Insurance Design should be defined to include the following:

- Value equals the clinical benefit for the money spent.
- Value-based benefit packages adjust patients' out-of-pocket costs for health services based on an assessment of the clinical benefit to the individual patient, based on population studies.
- The more clinically beneficial the therapy for the patient, the lower that patient's cost share should be. Higher cost sharing will apply to interventions with little or no proven benefit.[1]

In addition, we suggest the following:

[1] See http://www.sph.umich.edu/vbidcenter/about/.

- Value-Based Insurance Design should not limit the network to a point in which individuals cannot access free preventive service. For example, a plan should not be allowed to limit free preventive care to certain in-network providers who charge less for the services without any consideration for quality of and access to these services.

- Value-Based Insurance Design should not be used to increase costs beyond the restrictions in the ACA and associated regulations.

- Additional research is needed before applying value-based insurance design to multiple chronic conditions on a wide-scale basis. Demonstration and pilot programs should be implemented before broad-based programs are fully implemented.

- An appeals process should be available.

- Education for consumers in this area is critical. Special outreach efforts should be made to educate consumers about value-based insurance design.

- Additional oversight should be provided from HHS to determine the impact of these programs before broader implementation.

**4. <u>Primary Purpose Test</u>**

These interim final regulations clarify the cost-sharing requirements when a recommended preventive service is provided during an office visit. First, if a recommended preventive service is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit. Second, if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit. Finally, if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

At best, this would leave consumers without a clear understanding of when they would be responsible for a co-payment or other cost-sharing, and at worst, would leave them subject to billing "games" between the provider and the insurer. It is not unreasonable to think that a consumer could end up paying the co-payment at the physician's office until the provider and the insurer work out whether the visit is subject to co-payment. We do not see any straightforward way of resolving the confusion this rule creates, and for this reason we support elimination of the primary purpose test.

**5. <u>United States Preventive Services Task Force's Structure and Processes</u>**

The AHA/ASA values the work of the USPSTF, and we applaud the elimination of cost-sharing for USPSTF recommended preventive services. However, we urge the Secretary of Health and Human Services to reevaluate the structure and processes of the USPSTF, given its new role as a coverage recommendation body.

With its new and expanded role, the USPSTF should be retooled to increase the transparency of its processes and its inclusiveness. For example, we recommend that the USPSTF increase its membership

beyond the traditional base of primary care clinicians to include recognized and appropriately credentialed clinicians with expertise in the specific disease states that the recommended services are intended to prevent or detect.

Further, we believe the USPSTF processes should be more open to external input and should develop mechanisms to better engage external stakeholders in its deliberations and decision-making. AHA/ASA has called for the following improvements:

- The USPSTF partner organizations should be expanded to include those that can provide additional consumer representatives, particularly consumer organizations with expertise in the development of clinical guidelines for preventive services.

- Regular and frequent opportunities for public comment, including opportunities for public testimony, should be established to inform the identification of topics for the USPSTF's consideration, the development of evidence reports and the issuing of recommendation statements. These opportunities should be developed in a way that continues to preserve the objectivity and scientific basis of the final recommendations.

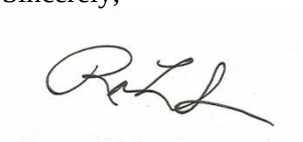
- All draft proposed recommendations should be subject to public input before being finalized. We applaud the USPSTF's recent steps in this direction.

**6. <u>Reviewing and Updating Preventive Services</u>**

AHA/ASA encourages the HHS Secretary to develop a process for reviewing and updating coverage of existing preventive benefits to reflect new prevention science as it emerges. In particular, HHS should review the allowable frequency for receiving preventive services, as well as the allowable scope of the benefits (e.g., the number of allowable hours or visits for a particular benefit). It should promptly update and amend guidance to plans and issuers consistent with ACA when the science supports updating. HHS also should regularly monitor the development and release of leading clinical guidelines from patient and provider groups to inform this process. Most recommendations are updated on some interval basis to reflect the expanding evidence-base and need to be monitored so preventive services remain current.

We thank you for the opportunity to comment on these important regulations to ensure coverage of preventive services. If you have questions about these comments or require additional information, please do not hesitate to contact Sue Nelson, at 202-785-7912 or on sue.nelson@heart.org.

Sincerely,



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