American Heart Association | American Stroke Association

January 25, 2013

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Room N–5653
Washington, DC 20210

Re: Wellness Programs

Dear Ms. Turner and Ms. Baum:

On behalf of the American Heart Association (AHA) the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate this opportunity to provide comments on the proposed rule, "Incentives for Nondiscriminatory Wellness Programs in Group Health Plans" promulgated by the Department of Labor, the Department of Health and Human Services (HHS), and the Department of Treasury (referred to here as the Departments).

The American Heart Association is a strong supporter of comprehensive employee wellness programs. We believe that health promotion initiatives provided at the worksite are critical to achieving our goal of improving the cardiovascular health of all Americans and reducing cardiovascular and stroke mortality by 20 percent by 2020. However, we also believe that the use of rewards and penalties tied to health status should not jeopardize an employee's access to affordable, quality health care or be used as subterfuge for discrimination based on health status.

As an organization that relies on rigorous, scientific evidence as the basis for our policies, we concur with the Departments' assertion that there is insufficient peer-reviewed research demonstrating the efficacy of financial incentives in motivating long-term behavior change.[1] However, it is likely that employers will continue to experiment with these and other approaches to try to improve employee health, increase productivity and lower health care costs. It is therefore critical that financial incentives and penalties intended to motivate behavior change are designed in a way that protect employees from discrimination based on health status and preserve access to affordable, quality health care.

We recognize that the majority of employer-based wellness programs are participatory in nature and do not require a specific outcome other than participation to receive a reward. The primary focus of our comments is on health-contingent wellness programs, although we recognize the importance of well-designed participatory programs and encourage their continued use.

We agree that it is important that employers retain flexibility in designing incentives that meet the needs of their employees and can be implemented without overly burdensome requirements. However, as noted in the 2006 preamble to the final rule, it is also important to include "certain requirements on wellness programs providing rewards that would otherwise discriminate based on a health factor in order to ensure that the exception for wellness programs does not eviscerate the general rule contained in HIPAA's nondiscrimination provisions."

The goal of the HIPAA nondiscrimination provisions is to preserve access to affordable group health plan coverage for individuals with health conditions. As the Departments explained in 2006, "Increased access fosters expanded health coverage, timelier and more complete medical care, better health outcomes, and improved productivity and quality of life." The uninsured with cardiovascular disease experience higher mortality rates and are less likely to have access to timely and appropriate care than their insured counterparts.[2,3] The suggestions made by AHA in response to the current proposed rule are intended to help preserve access and affordability of coverage, particularly for those who need it most.

We applaud the Department for providing additional clarification on standards set for health-contingent wellness programs and agree that these new rules should apply to both grandfathered and non-grandfathered group plans. We believe that the modifications in the proposed rule are designed in a way that improves the health of high-risk individuals and reduces the risk that health-contingent incentives are merely used to shift costs to higher-risk individuals.

We do however have suggestions in a number of areas that may help clarify the intent of the proposed rule and assure necessary consumer protections. We have organized our comments based on the questions posed by the Departments in the preamble to the rule.

The Departments invite comments on the apportionment of rewards in health-contingent wellness programs (which may involve tobacco use and/or other health factors) – for example, should the reward be prorated if only one family member fails to qualify for it.

Almost a quarter of companies' medical costs per year are spent on ten modifiable risk factors with obesity contributing the most at $347 per capita, per year.[4] Employers, employees, and their families share the financial burden of these health conditions through higher health care costs. Under the proposed rule, both the benefits (in the form of lower cost-sharing) and any additional costs (in the form of surcharges or penalties) can extend beyond the individual employee to immediate family members. However, the regulation should make it clear that in order to qualify for the reward or penalty family members must have full and complete access to a reasonably designed wellness program and that it is the same or similar to the one offered to the employee. The statutory language relevant to this provision clearly states that the dependents must be eligible to participate "fully" in a wellness program if the reward amount is based on the cost of coverage for which the employee and any dependents are enrolled.

We recommend that the final rule state that dependents subject to a health contingent wellness program who fail to meet a prescribed biometric or outcome standard must be offered an alternative standard or alternative means of qualifying that is readily accessible to those individuals and imposes no financial burden. Only then should the reward or penalty be prorated to the premium attributable

to each family member based on the difference between the cost of a family and individual plan. When family members are making an effort to improve their health status with accessible and affordable resources and appropriate medical oversight when warranted, they should be able to avoid the health care cost penalty or receive the full reward. When family members do not have full and complete access to programs and resources, the full reward or penalty should be apportioned to the employee only. A clear and well-communicated appeals process (discussed later in these comments) should be available to family members and dependents subject to the penalties and rewards.

The Departments invite comments on the proposed approach for coordinating the implementation of the tobacco rating factor under PHS Act section 2701 with the nondiscrimination and wellness program provisions.

Affordable health insurance coverage is critical for employees who use tobacco products. The AHA believes that all employees should be offered full and comprehensive tobacco cessation counseling as part of their benefits package, and that no penalty in the form of higher premiums should be allowed if such coverage is not provided. The rule should clearly state that any tobacco surcharge must be waived for individuals enrolled in a tobacco cessation program and that employers must continue to offer alternative standards that include a level of participation sufficient to achieve positive results based on what is known about intervention efficacy for multiple quit attempts.

To avoid the tobacco surcharge, employees should be allowed to take advantage of cessation programs at the workplace or enroll in community-based cessation programs. These cessation programs should include pharmacotherapy and counseling that can help smokers, as well as smokeless tobacco product users and e-cigarette users. Under the Affordable Care Act, all individual and small group health plans are required to offer tobacco cessation services with no cost-sharing. However, current health plan coverage of these services remains uneven. Tobacco users vary in terms of the tobacco products they use, the amount and frequency of use, and co-existing medical conditions they may have. When quitting, they need access to a range of treatments appropriate to their level of addiction to find the most effective approaches that work for them.

The proposed rule requests comments on possible definitions of "tobacco use." When defining "tobacco use," it is important to determine how "use" will be assessed (self-report vs. cotinine test), what tobacco products will be included in the definition (cigarette, cigar, smokeless tobacco product, etc.), and the amount of tobacco that meets the threshold for use. We will address these three issues separately. The goal of defining tobacco use should be to provide a simple and precise assessment of the consumer's tobacco use status that minimizes misunderstandings or potential false reporting and accounts for changing trends in tobacco products and uses.

First, with respect to how use will be assessed, we believe that the Departments should recommend to employers and health care plans that self-reporting is the preferred way to assess tobacco use. Although this would not prevent employers from using the cotinine test, we believe cotinine testing poses greater disadvantages over self-reporting, and can be burdensome for insurers, employers, and individuals. For instance, non-smokers can test positive if they have been exposed to second-hand smoke, and these tests cannot differentiate between a tobacco product and a cessation aid. For these and other reasons, self-reporting is the most common method of assessing tobacco use among insurers and employers today and should be encouraged.

Self-identification as tobacco users is not without problems. Unintentional, inaccurate self-reporting on the part of individuals could expose them to paying the surcharge unnecessarily, to significant financial liability, or even future accusations of fraud that could subject them to a policy rescission by the insurer. For these reasons, HHS should clarify that if there has been a misrepresentation, intentionally or unintentionally, there should be an appeals process for people who say they misunderstood the question and can sign an affidavit accordingly.

Because of the potential adverse consequences of inaccurate self-reporting, the question should be posed to enrollees in a simple, straightforward, precise way that will result in an unambiguous answer. For example, individuals who smoke the occasional cigarette or cigar in social situations may not consider themselves to be a "tobacco user" and may answer "no" to a question about whether they regularly smoke. Similarly, employees who use a tobacco product such as dip or chew may not consider themselves a smoker or tobacco user. These individuals should not unknowingly subject themselves to accusations of fraud because of ambiguities in the question. Because of the complexity of defining tobacco use, HHS should require that questions designed to assess tobacco use be developed to minimize the likelihood of inaccurate self-reporting and include examples.

Second, determining what tobacco products are to be included in the definition of "tobacco use" is complicated. There is no uniform, widely-used definition of tobacco use today. Moreover, the issue is becoming more complex as the tobacco industry continues to introduce new products to expand its market penetration (for example, e-cigarettes, dissolvable tobacco, etc.). We recommend that the general definition of tobacco use be based on the tobacco products FDA has the authority to regulate, and written into insurance applications so it is clear to the layperson which products are included. FDA's tobacco regulations currently apply to cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco, with the opportunity to extend authority to any other tobacco products deemed to fit the definition. These products could include cigars, cigarillos, snus, dissolvable tobacco, or any other product with nicotine that is derived from tobacco.

Finally, determining the amount of tobacco that constitutes "use" is also difficult. While there is no "safe" amount of tobacco use, there are also no consistent standards for what constitutes regular tobacco use among health plans and health status surveys. It is critical that the standard set for the amount of tobacco be unambiguous. Because there is currently no standard definition of tobacco use, HHS should use its planned consumer-testing program of the uniform enrollment application to evaluate various language, questions, and definitions of tobacco. After evaluating the results, HHS should apply the most reliable and consistent measure of actual tobacco use.

There are a number of different examples that HHS could consider for testing. For instance, the World Health Organization considers someone a "regular" tobacco user if they use at least one tobacco product a day. HHS could test variations of this definition that list specific tobacco products and includes a 30-day retrospective timeframe to assess which definition results in the most accurate and reliable responses from consumers. Until this research is completed, tobacco use, like all other health factors, should have a well-defined and well-communicated appeals process that would include a retest or alternative test, thereby providing employees with invalid test results an avenue for correcting the error.

The Departments invite comments as to whether additional rules or examples would be helpful to demonstrate compliance with the limitation on the size of the reward when the amount of the reward is variable and is not determinable at the time the reward is established (for example, when the reward is waiver of a copayment for outpatient office visits, the frequency of which will not be predictable for any particular participant or beneficiary under the plan).

The statute allows for a health-contingent incentive to be a waiver of all, or part, of a cost-sharing mechanism such as a copayment. We believe that the Departments should adhere to this language by only allowing rewards tied to copayments or other cost-sharing mechanisms to be full or partial waivers rather than increases in copayments. This restriction should preclude strategies that paid for any waiver of copayments by raising the overall cost of copayments across the board. Increases in copayments are known to deter individuals with chronic disease from seeking necessary care, a result that counters the overall goal of worksite wellness.

The Departments seek comments on whether any additional rules or clarifications are needed with respect to the process for determining a reasonable alternative standard.

The AHA applauds the Departments' decision to extend the reasonable alternative standard associated with health contingent programs to individuals who cannot meet the standards due to a medical condition or because of some other reason. However, the rules should clarify that the provisions for reasonable alternative standards also apply to the provision for alternative standards under reasonable design. We strongly suggest that one set of rules apply to alternative standards regardless of whether an employee has a specific medical condition or a health risk factor.

We offer the following additional suggestions for clarifying this portion of the rule:

- We support the Departments' recommendation that the individual's physician's prescription must be accommodated in the alternative standard and that the opinion of the personal physician preempts that of a medical professional acting as an agent of the employer or the plan. It is important that this provision be written in a way that explicitly applies broadly to any individual, including dependents if they are subject to a penalty or reward, associated with a medical issue. This can be most easily achieved by simply revising the language as follows:

  "If an individual's personal physician states that the employer's or plan's (or anyone acting on behalf of the plan or issuer) recommendations are not medically appropriate for that individual, the plan must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness."

- The rules should make it clear that employers must provide a timely response to requests for an alternative standard or a reasonable alternative means of qualifying and that the employee will not be penalized in any way during the interim period. The law requires that individuals have at least one opportunity per year to qualify for a reward in a health-contingent program. In addition, employees and their dependents should be able to adjust their program, or ask for an alternative standard anytime during the course of the year for medical reasons (e.g., pregnancy, cancer diagnosis, and acute injury) and remain eligible for the reward.

- The preamble states that when an employee fails at one or more attempts under the reasonable alternative standard provisions, he or she must be offered another attempt at the same alternative standard or a different approach. We support this approach, particularly for difficult behavior change, such as weight loss or smoking cessation, provided that the employees' level of participation in an alternative standard or program designed to help them achieve their goals is sufficient and reasonable based on what is known about their specific intervention and their physician's recommendations. We urge the Departments to specify this requirement in the regulations. We also strongly recommend that the Departments clarify that the intent is to provide this same accommodation to those seeking a reasonable alternative means to qualify for the reward if they are unable to meet a particular biometric standard.

- The preamble and examples provided in the rule suggest that the employer cover the costs of the alternative standard associated with medical conditions. We agree with this requirement and believe it should be clearly stated that this requirement also applies to the employee's family members if they are held accountable for the health-contingent program.

- We recommend that the rules make explicit that employees have the means to appeal when they do not feel that the standard or alternative standard is appropriate and when they want to appeal a determination that they failed to meet a standard. For health contingent programs, employers should have well-defined appeals, dispute, and retesting process that is transparent and effectively communicated to employees. To optimize confidentiality and credibility, employers should strongly consider having appeals independently adjudicated by a qualified vendor that specializes in this activity. In addition, the Affordable Care Act established an external appeals process under section 2719 of the Public Health Service Act that might serve as an appropriate mechanism for appeals made with regard to wellness programs.

- We urge the Departments to clarify that the alternative standard programs are easily accessible to employees as part of the definition of a reasonable design. As noted earlier, dependents should have easy access to programs if they are included in the incentive plan.

The Departments solicit comments on whether additional clarifications would be helpful regarding the reasonableness of physician verification.

We support giving employers the option, if reasonable under the circumstances, to request physician verification as part of a request for a reasonable alternative standard. However, we recommend that the Departments clarify that neither the physician nor the employee is required to disclose any details related to the particular medical condition(s). It should be sufficient for the personal physician to simply verify, as stated in the statute, that a health status factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy, or attempt to satisfy the otherwise applicable standard without providing any details about the specific medical condition.

We also believe that the rule, or at least the preamble, must provide additional clarification on procedures to ensure that the physician verification process needs to comply with HIPAA privacy and security requirements.

Our Joint Consensus Statement[5] maintained that any process that seeks documentation, particularly from a physician, of an employee's specific medical circumstances should be administered consistent with all legal requirements (e.g., HIPAA, state regulations) to assure personal health information is adequately protected. The AHA believes that employees should not be required to disclose a disability protected by the Americans with Disabilities Act, and that any medical information obtained as part of a wellness program that could identify a disability be kept confidential. In addition, the results of biometric screenings or reasons for obtaining an alternative standard should not be shared with the employer. Employers should receive aggregate, de-identified reports that stratify the population, classify risk and allow interventions to be targeted toward groups of unidentified employees. Stratification, categorization or grouping should not be done when there are not enough individuals in a group for each employee to remain anonymous.

Comments are welcome on whether certain standards, including evidence- or practice-based standards, are needed to ensure that wellness programs are reasonably designed to promote health or prevent disease. The Departments also welcome comments on best practices guidance regarding evidence- and practice-based strategies in order to increase the likelihood of wellness program success.

We believe it is important that the rules preserve some degree of flexibility so that employers can develop programs and approaches that meet the needs of their employees and can be implemented without overly burdensome requirements. However, since health-contingent programs can raise costs significantly for employees, it is critical that these programs have a clearly demonstrated potential for improving health. Reconciling these two objectives is a challenge; however, we suggest that the final rule consider the following approach.

We agree with the Departments that clarifications are needed to help prevent health-contingent wellness programs from providing little or no support to enrollees to improve individuals' health. While we support the attempts to accomplish this within the reasonable alternative standard framework, there should be some additional language specific to reasonableness of program design that insures that all participants in the wellness program are provided support to improve their health, especially in the lifestyle areas related to any health-contingent incentives. Thus, the rules should state explicitly that although a worksite wellness program can take many forms, a reasonably designed program must include a set of programs, resources, and worksite policies designed to promote health and prevent disease if health contingent rewards are incorporated into the design. The rules should make it clear that a reasonably designed program must consist of more than solely a biometric screening tied to a financial incentive or disincentive (in the form of surcharges or penalties).

We suggest the following language:

> "A reasonably designed program includes the following key elements: strategic planning, cultural support, programs for assessment and screening, behavior change interventions, engagement through communication and incentives, and evaluation."

These elements can be implemented in a variety of ways that are sensitive to the various types and sizes of workplace settings. The final rule should set forth several detailed examples of comprehensive, evidence-based program designs that could explicitly serve as safe harbors demonstrating compliance with the ''reasonably designed'' standard. The examples could serve as

safe harbors, so that a plan or issuer could then adopt a program identical to one described as satisfying the wellness program requirements in the examples and be assured of satisfying the requirements in the regulations. This provides some guidance and a safe harbor to assure programs are evidence-based while allowing employers flexibility in designing different programs and approaches to motivate individuals to improve their health.

We also recommend that the Departments go a step further and develop an approved checklist in addition to the sample program models that could serve as guidance. Completing this checklist would assure employers that they are offering programs consistent with evidence-based research and best practices. Our Consensus paper[5] provides a framework and adequate detail to develop such a simple checklist that employers would find easy to complete.

We would further suggest that HHS continue to evaluate programs and provide new models of successful approaches in various settings with different types and sizes of employers engaging individuals from diverse socioeconomic, educational, and cultural backgrounds.

The Departments invite comments on this approach, including on ways to ensure that employees will not be subjected to an unreasonable "one-size-fits-all" approach to designing the different means of qualifying for the reward that would fail to take an employee's circumstances into account to the extent that, as a practical matter, they would make it unreasonably difficult for the employee to access those different means of qualifying.

The AHA believes that the ideal health-contingent or participatory programs are individually-tailored and focused on the health and well-being of each employee. The AHA commends the Departments for supporting alternative means to qualify for rewards under the health-contingent programs.

We believe the term "overly burdensome" should take into account personal circumstances that may make it difficult or impossible for an employee to participate in wellness efforts. Those individuals for whom the program is overly burdensome should have the opportunity to receive an alternative standard or waiver.

Anticipating what may constitute "burdensome" for any individual is difficult. However, we recommend that at a minimum, the regulations themselves incorporate the language in the preamble that states that: "a reasonably designed program should take into account an employee's circumstances to the extent that, as a practical matter, those circumstances would make it unreasonably difficult for the employee to access those different means of qualifying."

Comments also are invited on whether any other consumer protections are needed to ensure that wellness programs are reasonably designed to promote health or prevent disease.

The AHA recommends the following clarifications in the proposed regulations to assure that wellness programs are reasonably designed and protect consumers from discrimination based on health status or reduce access to affordable health care.

- If the surcharges and penalties allowable under wellness programs make it too costly for individuals with health issues to participate in, or afford group health plan benefits, this could result in a loss of coverage for individuals in poorer health status – and consequently – poorer health. This could also mean an entire family might lose access to coverage. Older workers and those with cardiovascular disease could potentially face costly wellness penalties. The preamble to the 2006 rule, noted that "the Departments sought to avoid a reward or penalty so large as to have the effect of discouraging enrollment based on health factors, denying coverage, or creating too heavy a financial penalty on individuals who do not satisfy an initial wellness program standard." We strongly recommend that this point be reiterated in the final rule. **A surcharge should under no circumstances cause an employee to lose affordable employer-sponsored coverage.**

- For clarification in the final regulation, we encourage you to include additional detail as to the term "medical condition" to make it clear that it includes mental, behavioral, cognitive, and emotional conditions and limitations that may preclude an individual from meeting the standard to qualify for an incentive.

- Employers also should consider whether their incentive design is likely to place a greater economic burden on certain demographic groups of employees than others. The preamble to the regulation should encourage employers to consider their incentive design in this context. We also recommend that employers be required to submit demographic information about employees who participate in health contingent wellness programs. This information – which is likely collected routinely by the employer or program vendor – will help determine the impact of health contingent wellness programs on various demographic groups.

- Additionally, the Departments should extend the Rand/Care Continuum Alliance study to include data from the time frame in which these health-contingent programs are being implemented. It will be critical to integrate those data into an analysis on the impact of health contingent programs on employee health status, the effect of the wellness program in lowering costs for employers and employees, evidence of employee satisfaction or dissatisfaction with the wellness program and the impact on access to health care. It is important to understand the value of incentives used by employers and whether they are administered as rewards or penalties. Employers should be encouraged to partner with the research community to evaluate objectively the impact of their programs on employee health, access to health care, and the quality of programming to further our understanding of their efficacy.

- The Departments should clarify the definition of the term "health factor." The rules are unclear regarding the type of health factors considered reasonable other than they should be: related to health promotion or disease prevention programs; not be overly burdensome; not be a subterfuge for discrimination; and not be highly suspect in the method chosen. According to recent results from an annual market survey, of the companies responding to the survey, 90 percent with an outcomes-based program use a weight-related standard and 75 percent use blood pressure, cholesterol, and tobacco use.[5] We believe the use of a medical or physical illness, disability, and/or largely non-preventable conditions would not be considered a reasonable design and likely would violate antidiscrimination laws**. The AHA**

recommends that financial incentives should be limited to health status factors that are modifiable for many individuals through changes in health behaviors.

The health factors that would qualify under this definition include measurements of blood pressure, cholesterol, tobacco use, BMI/body weight, and physical activity/physical fitness. We do not consider glucose an appropriate measure and all references to it should be removed from the regulation. Screening and assessment for glucose levels are acceptable, but holding employees accountable for an outcome-based measure for glucose measures within a health-contingent program is inappropriate since high glucose levels are the definition of diabetes, which is a disease and in most cases, not a modifiable condition.

While we do not consider glucose an appropriate health outcome measure, the AHA does support including physical activity/physical fitness. There are a number of validated tools available that can be readily used across different employee groups in various settings to assess levels of physical activity or physical fitness. These include the Physical Activity Assessment Tool or Fitness Gram and measured reporting with pedometers or accelerometers.

These proposed regulations provide new sample language in the regulatory text and in examples that is intended to be simpler for individuals to understand and to increase the likelihood that those who qualify for a different means of obtaining a reward will contact the plan or issuer to request it. The Departments invite comment on the sample language in both the regulatory text and in the examples.

The sample language provided in the regulation mentions rewards that an employee may be able to obtain through the employer health plan. However, in some cases, the reward may be a surcharge, or lack of a surcharge. We believe it is critical that employees understand when the structure of the plan is subjecting them to a penalty just as they would be notified that they are eligible for a reward. We suggest the sample language include the following information:

- The standard or standards the employee is expected to meet to qualify for wellness program rewards or to avoid a penalty along with the financial consequences associated with nonparticipation.
- A clear explanation as to when and precisely how an individual may request an alternative standard or waiver along with the time frame for its completion.
- Contact information – both internal and external to the plan or company – that individuals can contact with questions or concerns about the company wellness program.

In addition, we encourage the Departments to require health plans to obtain verification that the employee has chosen not to participate in a wellness program when the result is higher high care premiums or other cost sharing.

Additional Suggested Resources:

Per the Departments' request, we recommend some additional resources that may provide further information on the link between health risk factors and health care costs, return on investment, the importance of worksite culture in promoting behavior change, the impact of worksite wellness within small business settings, and further description of a research agenda that could help maximize the impact of worksite wellness programs on the U.S. adult population.

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Summary

In conclusion, we appreciate the Departments' effort to clarify the requirements for health-contingent programs and support appropriately designed wellness programs and their role in transforming the health of adults in the workplace. We believe this proposed rule adds consumer protections within health-contingent programs that preserve flexibility for employers to foster innovation. We encourage the Departments to provide further clarification on the issues we have identified. If you have any questions or need any additional information, please do not hesitate to contact Laurie Whitsel, Ph.D., Director of Policy Research at 724-238-0272 or via e-mail at laurie.whitsel@heart.org.

Sincerely,

Donna K. Arnett, PhD, BSN
President, American Heart Association

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[1]Mattke S. Schnyer C. Van Busum KR. A review of the U.S. workplace wellness market. Rand Corporation. 2012.

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