

February 24, 2011

Secretary Timothy Geithner
U.S. Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

Secretary Hilda Solis
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Proposed changes to 71 FR 75014: Nondiscrimination Based on a Health Factor and Wellness Programs

Dear Secretary Geithner, Secretary Solis and Secretary Sebelius:

We are writing on behalf of the millions of patients, consumers, and workers that our organizations represent to comment on proposed revisions to final rules issued on December 13, 2006, related to Nondiscrimination and Wellness Programs in Health Coverage in the Group Market. These rules were promulgated by the Department of Treasury, the Department of Labor, and the Department of Health and Human Services (referred to here as the Departments).

A recent FAQ issued by the Department of Labor entitled, “About Affordable Care Act Implementation,”¹ noted that the Affordable Care Act (ACA) added a new section 2705 to the Public Health Service Act regarding nondiscrimination and wellness that largely incorporated the provisions of the Departments’ existing regulations with some modifications. One such change, effective in 2014, increased the maximum reward that can be provided under a health-contingent wellness program from 20 percent to 30 percent of the cost of employee health care coverage.

The Departments announced that they intend to propose regulations that use their existing regulatory authority to raise the percentage for the maximum reward to 30 percent before the year 2014. The Departments also stated that they will consider including new consumer protections in the regulations to prevent these programs from being used as a subterfuge for discrimination based on health status.

¹FAQs About Affordable Care Act Implementation Part V and Mental Health Parity Implementation, U.S. Department of Labor, <http://www.dol.gov/ebsa/faqs/faq-aca5.html>

The undersigned organizations applaud Congress and the Administration for their commitment to prevention and wellness. However, we are deeply concerned that without the inclusion of effective and enforceable consumer protections, the current regulations as modified, and section 2705 of the ACA, could be used as a backdoor to medical underwriting for individuals with pre-existing health conditions or disabilities. We urge the Administration to take prompt and appropriate action to protect consumers from paying higher premiums for insurance coverage based on their health. These kinds of discriminatory practices undermine a basic principle of the ACA – the elimination of ratings based on health status – that was critical to our support for the legislation.

Our organizations strongly support companies that bring evidence-based wellness programs to the workplace, using positive – rather than punitive – strategies. We know that many comprehensive workplace wellness programs improve employee health and lower medical costs² – serving as a “win-win” for both the employer and the employee. However, under the current regulations, a wellness program can be little more than a set of financial penalties based on an individual’s weight, Body Mass Index (BMI), waist circumference, blood pressure, cholesterol, blood glucose level, or some other set of health factors.

Though described as financial incentives or rewards, the difference between an incentive and a penalty can be illusory. Two different wellness programs – one with rewards, the other with penalties – can be designed to have the same impact on company budgets. The baseline employer contribution can be set low, with employees allowed to earn rewards for meeting benchmarks, or it can be set high, with employees being penalized for failing to meet benchmarks. These kinds of minimal incentive programs strongly resemble medical underwriting in the individual market as shown in the chart below.

Wellness Penalties/Medical Underwriting	
<u>Wellness Program</u>	<u>Medical Underwriting</u>
<ul style="list-style-type: none"> • Enrollee completes health risk assessment, provides info about health status/history 	<ul style="list-style-type: none"> • Applicant completes underwriting form, provides info about health status/history
<ul style="list-style-type: none"> • Submit biometrics (e.g., blood and urine samples, cheek swab) 	<ul style="list-style-type: none"> • Submit biometrics (e.g. blood and urine samples, cheek swab)
<ul style="list-style-type: none"> • Premium increased by \$4,200/year if blood pressure, cholesterol, glucose levels above normal 	<ul style="list-style-type: none"> • Premium increased by \$4,200/year if blood pressure, cholesterol, glucose levels above normal

² Carnethon M, Whitsel LP, Franklin BA, Kris-Etherton P, Milani R, Pratt CA, Wagner GR; on behalf of the American Heart Association Advocacy Coordinating Committee; Council on Epidemiology and Prevention; Council on the Kidney in Cardiovascular Disease; and Council on Nutrition, Physical Activity and Metabolism. Worksite wellness programs for cardiovascular disease prevention: a policy statement from the American Heart Association. *Circulation*. 2009;120.

There is limited independently evaluated research that shows that varying the cost of employer-sponsored insurance will have an impact on health outcomes, and what research exists is mixed.³ Some success has been shown for smoking cessation^{4, 5} or for improving participation rates in some kinds of wellness programs.⁶ However, there is very little – if any – empirical evidence that financial rewards can result in sustained weight loss.⁷ On the other hand, there is ample evidence that patients are far less able to manage chronic conditions such as hypertension or diabetes when they have high deductible benefit designs requiring significant cost-sharing.⁸ A major goal of health reform was to remove barriers to health care for individuals with preexisting health conditions – not impose new ones.

Penalties tied to health outcomes may also place certain individuals and populations at a disadvantage, especially those that face environmental or socioeconomic barriers to changing their lifestyle or health status. These challenges include child or elder care obligations, unsafe walking/biking trails, limited access to recreational facilities, the need to hold a second or third job, and limited access to healthy, affordable foods. Unfortunately, it is often the low-income or least-educated employees who face these obstacles and disproportionately suffer health disparities.⁹ Studies have also found that overweight, obesity, hypertension, and high cholesterol have a genetic predisposition and are strongly connected with age. Therefore, premiums tied to health metrics may penalize individuals for factors they simply cannot control.¹⁰

A tough economic climate and rising health care costs have helped spawn a proliferation of programs using premium differentials to control the cost of health benefits.^{11,12} A survey by Hewitt of nearly 600 large U.S. employers (representing more than 10 million employees) found that nearly one-half (47 percent) already use or plan to use financial penalties over the next three to five years for employees. Of those companies using or planning to use penalties, the majority (81 percent) say they will do so through higher benefit premiums. Increasing deductibles and out-of-pocket expenses were also cited as possible penalties.¹³ These trends are to some degree a response to escalating healthcare costs and the desire to shift more costs to consumers.¹⁴

Unfortunately, existing regulations fail to provide sufficient protections from employers who believe they should be able to charge individuals based on the estimated cost of their health status – regardless of whether or not penalties have any impact on these behaviors and

³ Ibid.

⁴ Volpp, Kevin F. et al, A Randomized, Controlled Trial of Financial Incentives for Smoking Cessation, *N Engl J Med* 2009; 360:7, 699-709.

⁵ Matson, Dyann M. et. Al, The Impact of Incentives and Competitions on Participation and Quit Rate in Worksite Smoking Cessation Programs, *Am J. Health Promotion* Mar./April 1993, 7;4,270-80.

⁶ Jeffrey, Robert W., et. Al, Empirical Evaluation of Effectiveness of Tangible Incentives in Increasing Participation and Behavior Change in a Worksite Health Promotion Program, *Am J Health Promotion* Nov/Dec 1993: 8;2, 98-100.

⁷ Paul-Ebhohimhen and Avenell 2007.

⁸ Hall, JP, Carroll SL, Moore JM. Health care behaviors and decision-making processes among enrollees in a state high-risk insurance pool: focus group findings. *American Journal of Health Promotion*. May/June 2010. 24.

⁹ Lewis, R. J., W. W. Huebner, et al. (1996). "Characteristics of participants and nonparticipants in worksite health promotion." *Am J Health Promotion* 11(2): 99-106.

¹⁰ Johannes J. Bairey Merz CN. Is cardiovascular disease in women inevitable? Preparing for menopause and beyond. *Cardiol Rev*. 2011 Mar-Apr;19(2):76-80.

¹¹ Mello, Michelle M., et al. (2008). "Wellness Programs and Lifestyle Discrimination – The Legal Limits: *N Engl J Med* 359:2, 192-199.

¹² Okie S. The Employer as health coach. *N Engl J Med* 2007; 357:1465-9.

¹³ <http://www.hewittassociates.com/Intl/NA/en-US/AboutHewitt/Newsroom/PressReleaseDetail.aspx?cid=8256>

¹⁴ Healthcare Intelligence Network (HIN).

ultimately, on the employee's health. We believe the decision by the Departments to reopen the current regulations is timely, providing that any changes to the regulations include strong safeguards for individual employees and their families. The financial ramifications for employees may be significant and the absence of strong protections against cost-shifting to less healthy employees could undermine important new affordability provisions contained in the ACA.

We would prefer that wellness programs be prohibited altogether from varying an individual's insurance premiums or cost-sharing amounts due to a health factor. The background and comments below provide our recommendations for regulatory and enforcement provisions that we believe would provide necessary protections for employees under the existing law and regulations. The ultimate goal is to make certain that Americans are not penalized financially for preexisting health conditions – including those with chronic diseases and disabilities – and that access to care becomes more, rather than less, affordable.

Recommended Revisions

The following sections provide recommended changes or expansions to existing regulations that will help protect employees and consumers, while giving employers the flexibility to design programs that are innovative and not overly burdensome. These proposals are organized around specific requirements in the current regulations and the ACA, including:

1. A wellness program shall be reasonably designed to promote health and prevent disease;
2. A wellness program shall not be overly burdensome;
3. A wellness program shall not be a subterfuge for discriminating based on a health status factor;
4. A wellness program shall allow for a reasonable alternative standard and must disclose in all materials describing the terms of the program, the availability of a reasonable alternative standard (or the possibility of a waiver of the initial standard); and
5. The cost of health care coverage shall remain affordable.

1. A wellness program shall be reasonably designed to promote health and prevent disease.

The current Health Insurance Portability and Accountability Act (HIPAA) regulations state that a reasonably designed program must have a reasonable chance of improving the health of participants and cannot be highly suspect in the method chosen to promote health or prevent disease.¹⁵ However, the supplemental information provided with the regulatory language contradicts this statement, explaining that:

“the reasonably designed requirement is intended to be an easy standard to satisfy...there does not need to be a scientific record that the method promotes wellness to satisfy this standard. The standard is intended to allow experimentation in diverse ways of promoting wellness. For

¹⁵ See 71 FR 75036, December 13, 2006.

example, a plan or issuer could satisfy this standard by providing a reward to individuals who participated in the course aromatherapy.”¹⁶

In other words, an employer can offer a course in aromatherapy and then penalize an employee for not reaching a certain weight. Such arbitrary programs without a strong evidence-base to support them illustrate the need for a clear definition of reasonable design that is based on evidence.

Employee wellness programs have grown in size and number in the last several years, along with the evidence base that supports best practices. Several public and private organizations have established criteria for what constitutes an effective program. In addition, two provisions of the ACA address best practices in workplace wellness. Section 10408 creates a grant program to assist small businesses in providing comprehensive workplace wellness programs. This new program – which recently received funding from the Prevention Trust Fund – requires the Secretary of Health and Human Services to develop specific program criteria that are based on research and best practices, and outlines four elements of a comprehensive program. These include:

- Health awareness initiatives (including health education, preventive screenings, and health risk assessments);
- Efforts to maximize employee engagement (including mechanisms to encourage employee participation);
- Initiatives to change unhealthy behaviors and lifestyle choices (including counseling, seminars, online programs, and self-help materials); and
- Supportive environments (including workplace policies to encourage healthy lifestyles, healthy eating, increased physical activity, and improved mental health.)

Section 4303 of the ACA, requires the CDC to provide employers with technical assistance and other tools to evaluate workplace wellness programs and requires the Secretary to develop program criteria that are based on and consistent with evidence-based research and best practices. These include research and practices as provided in the Guide to Community Preventive Services, the Guide to Clinical Preventive Services, and the National Registry for Effective Programs.

The Health Enhancement Research Organization (or “HERO”) is another organization that has developed criteria for wellness programs. In the coming months, HERO plans to release standards for worksite wellness programs that have a strong evidence-base.¹⁷ HERO is partnering with MERCER Health Systems to collaborate and co-own a large-scale, interactive employee health management benchmarking and best practice normative database. Employers can use this database to compare their own programs with best practices and data from other demographically similar programs.

¹⁶ See 71 FR 75018, December 13, 2006.

¹⁷Health Enhancement Research Organization. http://test2.the-hero.org/about_hero.htm.

Recommendations

- An employer-based wellness program that varies the costs of employer-sponsored coverage to attain specific health outcomes must be evidence-based and in line with best practices as specified by a credible nonprofit organizations that has been certified by the Secretary of Health and Human Services.
- All such programs that are reasonably designed and not suspect in their methods would be required at a minimum to meet the following tests:
 - Plans must provide evidence-based opportunities and programs that are accessible and at no cost to the employee and do not necessitate the use of employee leave for required activities, including doctor's visits.
 - Wellness programs must provide a reasonable period of time for an employee to meet or to make progress towards a health target or standard (or alternative option for meeting the target or standard) that takes into consideration personal health status and guidance from the employee's personal physician; and
 - The size of the premium or cost sharing variation should be based on the best possible evidence about what it takes to motivate change for a behavior or risk factor being targeted. Simply picking 30 percent of the cost of insurance and applying it across the board would not constitute a reasonable design.

Enforcement

All plans would be required to submit an independent evaluation of their programs every three years. Employers that fail to follow best practices would be subject to fines and penalties and also be required retroactively to reimburse employees for any additional costs paid or incentives denied based on a program that did not meet evidence-based criteria.

2. A wellness program shall not be overly burdensome.

The current regulations state that the wellness program cannot be overly burdensome, but offer little guidance as to what that means or to whom it applies.

The supplemental information accompanying the regulation states that there should be “no overly burdensome time commitment or a requirement to engage in illegal behavior” (presumably on the part of the employee). Another reference notes that in devising wellness programs, “plans and issuers should strive to improve the health of participating individuals in a way that is not administratively burdensome or expensive.” Clearly, the term “overly burdensome” is not well defined.

Recommendations

- The term “overly burdensome” should take into account personal circumstances – including family care giving responsibilities or multiple jobs – that may make it difficult or impossible for an employee to participate in wellness efforts that take place outside normal work hours. For example, participation in a weight loss program that only meets in the evenings without available child care could pose a significant hardship on low-income single parents. A program that is located in an area not served by public transportation could likewise pose a

hardship. Individuals for whom the program is overly burdensome should have the opportunity to receive an alternative standard or waiver.

- Individuals who receive an alternative standard or waiver due to the overly burdensome criteria should receive the same benefits as those who receive the same due to a medical condition.
- The ability of some adult dependents to participate in a worksite wellness program requiring satisfaction of a standard related to a health status factor is diminished because of medical, economic, social, geographic, or other reasons. The regulations should clarify that such dependents should either not be considered “fully” able to participate, or not be eligible for program inclusion – and therefore should not be subject to a penalty for non-participation. The ACA - which largely codified these regulations – noted that the reward or penalty for a wellness program should not exceed 30 percent of the cost of coverage including dependents unless those dependents ay “fully” participate in the program.

Enforcement

See section on *reasonable alternative standards*, below.

3. A wellness program shall not be a subterfuge for discriminating based on a health status factor.

The current guidance does not clearly define the term “health status factor” with respect to wellness programs. However, section 2590.702 of the regulations states that : “The term health factor means, in relation to an individual, any of the following health status-related factors: (1) Health status; (2) Medical condition (including both physical and mental illnesses); (3) Claims experience; (4) Receipt of health care; (5) Medical history; (6) Genetic information; (7) Evidence of insurability; or (8) Disability.”¹⁸

It is clear from this broader definition that there is no real difference between a health status factor and a pre-existing health condition. Indeed, probably the most widely-praised aspect of the ACA is ending discrimination based on pre-existing conditions such as heart disease, diabetes, and cancer. Thus, it is essential that workplace wellness programs not become a subterfuge for the medical underwriting that the Act was intended to eliminate.

This can happen in a number of ways. The first is by rating people based on health outcomes that are little more than symptoms or medical markers of a chronic disease. Perhaps the most blatant of these is a penalty (or incentive) based on blood glucose levels. Having high blood glucose is the essence of diabetes, so such a factor will *only* apply to people with diabetes. Measures of blood pressure – which can indicate the existence of the cardiovascular disease or hypertension – is another example.

Second, health status should not be a subterfuge for discrimination based on race, ethnicity, sex, or age. Genetics, cultural backgrounds, age, and a variety of environmental factors including family responsibilities, make losing weight – a health outcome that is closely linked to diabetes and levels of hypertension, and cholesterol – harder for some people than for others.

¹⁸ 71 FR 239, December 13, 2006.

The guidance does make it clear that wellness regulations may not supersede protections included in the Americans with Disabilities Act (ADA), the Age Discrimination in Employment Act (ADEA), or any other federal or state civil rights law. The regulations state that employers, plans, issuers, and other service providers should consider the applicability of these laws to their coverage and contact legal counsel or other government agencies such as the EEOC and State insurance departments if they have questions under those laws.¹⁹ For example:

- The Genetic Information Nondiscrimination Act (GINA) restricts an employer's ability to inquire about family health history or other "genetic information" as part of a program of wellness incentives under a group health plan. In connection with any group health plan or health insurer, GINA prohibits the covered entity from: (1) increasing the group premium or contribution amounts based on genetic information; (2) requesting or requiring an individual or family member to undergo a genetic test; and (3) requesting, requiring or purchasing genetic information prior to or in connection with enrollment, or at any time for "underwriting purposes."
- The Americans with Disabilities Act, as amended by the ADA Amendments Act, limits an employer's ability to make disability-related inquiries and to require medical examinations. Generally, the examination or inquiry must be made on a post-offer basis for employment and either be "job-related and consistent with business necessity," or a voluntary medical examination as "part of an employee health program available to employees at that work site." Wellness plans and health risk assessments may be prohibited under the ADA's "no medical exams or inquiries" provision unless they are voluntary. The level of inducement or more specifically, the value of the incentive for taking the health risk assessment may impact whether the medical examination or inquiry is truly voluntary. A wellness program that discriminates against individuals with disabilities or fails to make reasonable accommodations for individuals with disabilities subjects an employer to liability under the ADA.
- An employer could violate Title VII of the Civil Rights Act of 1964 if its wellness program resulted in disparate treatment or caused a disparate effect on the basis of race, sex, or national origin. For example, if a particular medical condition is more common in individuals of a certain race, national origin, gender or religion and that medical condition resulted in higher premiums being paid by that protected class, this implicates Title VII protections. For the wellness program to be permissible, the employer would have to show it is job-related and consistent with business necessity.
- The Age Discrimination in Employment Act prohibits discrimination against individuals age 40 and over. A program that provides cash rewards for employees within a certain bone density range, for example, could violate the Act.

¹⁹ 71 FR 75038 December 13, 2006.

Wellness programs also implicate a variety of state and local laws. For example, many states have "lifestyle statutes" that prohibit employers from regulating or monitoring an employee's legal off-duty conduct.

Recommendations

- Health outcomes that are explicitly markers for chronic disease states should be strictly banned. Thus, a health outcome around high blood sugar would not be allowed as it is the defining characteristic of diabetes and is found only in people with this disability. This does not strictly ban markers such as obesity that may be correlated with a number of disabilities.
- Individuals with a diagnosis of diabetes, heart disease, hypertension, cancer, obesity, mental illness, or some other disease should remain under the close supervision of their own personal physician and offered an alternative standard or granted a waiver.
- Any alternative program must be designed in deference to the advice of the individuals' own doctor.
- The costs of physician or other medical visits required by a wellness program must be fully covered by the individual's employer or employer-based insurance plan.
- Communications between employee and employer with regard to their health condition, and any monitoring of patient compliance of any alternative plan should be conducted in a manner highly protective of the doctor-patient relationship as well as employee confidentiality. For example, employers should be strictly prohibited from seeking verification of an enrollee's medication compliance.
- Wellness programs must be explicitly prohibited from requiring the use of medications or medical procedures to meet health-outcomes based standards.
- The size of a financial penalty that renders a wellness program no longer voluntary must be addressed across the board – regardless of whether the program is focused in participation or on outcomes. Premium variation of the amounts contemplated by this regulation could represent financial coercion that is not voluntary in nature, particularly for individuals of limited means.
- The regulations must reaffirm that HIPAA wellness regulations will not supersede or undermine core policies or legal protections contained Title VII of the Civil Rights Act, the Age Discrimination in Employment Act, the Americans with Disabilities Act, the Genetic Information and Nondiscrimination Act, the Family Medical Leave Act, and Section 1557 of the Affordable Care Act, or any other Federal or State civil rights law.

Enforcement

The Secretary of Labor may impose a penalty against any sponsor of a group health plan, or any health insurance issuer offering a wellness program, for any failure by such sponsor or issuer to meet the standards and requirements of all relevant non-discrimination provisions in all materials that describe the wellness program.

Employees should be properly notified of their rights and obligations under such programs and informed about who to contact with complaints about a wellness program; the Department of Labor should provide model language for employers to use. In addition to damages available under applicable civil rights laws, employers should be required to retroactively reimburse

employees for any additional costs paid or incentives denied based on a program that discriminates based on a health status factor.

4. A wellness program shall allow for a reasonable alternative standard and must disclose in all materials describing the terms of the program the availability of a reasonable alternative standard (or the possibility of a waiver of the initial standard.)

Under the current regulations, a wellness program that provides a reward requiring satisfaction of a standard related to a health factor must provide a reasonable alternative standard for obtaining the reward for certain individuals. This alternative standard must be available for individuals for whom it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard, or for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

Recommendations

- An “alternative standard” should be available for individuals based on medical conditions and for those for whom participation is overly burdensome (see section above).
- Employees must have the right to request an alternative standard at any point in time, due to changes in their life circumstances or health status change.
- The terms “medical condition” and “medically inadvisable” should be clearly defined under the alternative standard language along with the circumstances that make it “reasonable under the circumstances” to request verification of the alternative standard request.
- Employees’ medical privacy is paramount and must be protected throughout any process used to develop a reasonable alternative standard. Strong measures should be in place to protect employee health information including an employer affirmation of compliance with the HIPAA medical privacy regulation. While employers may seek verification that a health factor makes it medically inadvisable for an individual to meet a standard, an employee must not be required or asked to disclose to employer or the health plan the specific medical condition affiliated with a request for an alternative standard or waiver of the standard.
- If the employer does not offer the participant an outright waiver, the employer must provide the alternative program to qualifying participants taking into consideration any input from the participant and deferring to the advice or recommendations of participant’s doctor. Employees should be given ample time to get an appointment with a health care provider to assist in developing an alternative option if necessary.
- The design of the alternative program and the cost of that alternative, including the patient costs of necessary physician or other medical appointments needed to develop the alternative, should be the employer’s responsibility.
- Employers must provide a timely response to requests for alternative standards.
- The employee should be eligible for the wellness program reward (or not be subject to the penalty) if a waiver or alternative standard is granted.
- Employees who qualify for a waiver or alternative standards should have their premiums adjusted retroactively if they win an appeal against an unfair surcharge.
- For complaints related to denials for alternative standards or waivers, or for employees who believe that they are inaccurately charged a surcharge (or denied a reward), the individual should be able to request an independent, external review. The ACA requires health plans to

have in place both internal and external appeal processes for claims denials and the regulations should clarify that employees in wellness plans will be guaranteed appeal rights if they think the regulations governing these plans have been breached.

- Disclosure to employees about the use of reasonable alternative methods should be transparent and comprehensible. The disclosure should be included in all materials that describe the terms of the wellness program.

Enforcement

Employers shall be assessed a penalty if plans fail to meet the requirements for waivers and alternatives standards or to provide full and adequate disclosure of the operational details of their wellness program including the availability of a reasonable alternative. Employers shall also be required to retrospectively reimburse employees for any additional costs paid or incentives denied because of their failure to comply with these regulations. The Secretary of Labor may impose a penalty against any plan sponsor of a group health plan, or any health insurance issuer offering a wellness program, for any failure by such sponsor or issuer to meet the standards and requirements of the HIPAA Privacy Rule. Employees should be properly notified of their rights and obligations under such programs; the Department of Labor should provide model language for employers to use.

5. The cost of health care coverage must remain affordable

The total amount of any variation in premium or cost sharing that may be imposed under a wellness plan is limited, but the regulations make it clear that plans may vary benefits in either direction – and that penalties are permissible. The regulations state that:

*“a reward can be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan” (emphasis added).*²⁰

The explanatory notes also say that:

*“Possible outcomes include a shifting of costs to plan sponsors from participants who satisfy wellness program standards, from plan sponsors to participants who do not satisfy the standards, from participants who satisfy the standards to those who do not, or some combination of these.”*²¹

Under the current rule, premium variation for standards related to a health factor must not exceed 20 percent of the cost of employee-only coverage under the plan. However, if any class of dependents participates in the wellness program and the employee is enrolled in family coverage, employers may vary premiums or other costs by 20 percent of the total cost of employer-sponsored family coverage.

²⁰ 71 FR 75036 December 13, 2006.

²¹ 71 FR 75027 December 13, 2006.

According to the explanatory statement, “the percentage limit is designed to avoid a reward or penalty being so large as to have the effect of denying coverage or creating too heavy a financial penalty on individuals who do not satisfy an initial wellness program standard that is related to a health factor.”²²

The table below shows the size of the current and proposed premium variations based on average annual premiums for employer sponsored coverage (all plan types).

HIPAA Premium Variation Under 20%, 30% and 50% Scenario				
	Total Cost of Employer Sponsored Coverage	Amount of Incentive/Penalty		
		<u>20%</u>	<u>30%</u>	<u>50%</u>
Individual	\$5,049	\$1,010	\$1,515	\$2,525
Family*	\$13,770	\$2,754	\$4,131	\$6,885

Source: Average premiums as paid by employer and employee for family coverage in 2010 (all plan types), based on Kaiser/HRET annual survey of health plans.

*If any class of dependents is allowed to participate in the program and the employee is enrolled in family coverage, employers may vary coverage by these amounts.

ACA also established criteria regarding the amount, as a share of an individual’s or family’s income, that is considered an affordable cost for health coverage. Under Sections 1401 and 1402, the Act provides income-based premium tax credits and cost-sharing assistance to prevent individuals and families from spending more than these income-based affordability thresholds on health coverage and care. Further, under Section 1501, individuals and families are exempted from the individual responsibility requirements to either maintain coverage or pay a tax penalty if there is a “lack of affordable coverage”²³ available to them, defined in this section as the lack of health coverage options that cost 8 percent or less of household income (or do not otherwise cause them hardship). Additionally, individuals whose employer-based premiums cost more than 9.5 percent of their income may qualify for income-based tax credits for exchange coverage, and assessments may be imposed on their employers for not providing affordable employee coverage under the requirements of “shared responsibility for employers” in Section 1513 of the Act.

These provisions of the ACA are designed to ensure that the cost of health coverage and care is affordable to individuals and families, and that those who cannot secure affordable coverage are not penalized. Coverage and care costs that exceed the affordability thresholds of the ACA, including the costs of wellness incentives, would be “overly burdensome” for individuals and families and run contrary to the Act’s intent to make coverage “affordable.” And burdening sicker employees and their families with significant increases in their health care costs makes coverage less accessible for those who need it most. The result that must be avoided is cost increases through the imposition of wellness penalties and surcharges that force those who are already sick out of the health insurance market.

²² 71, FR, 75018, December 13, 2006.

²³ Section 1411(b)(5)(B)

Recommendations

- Dependents (which should exclude minor children) must be able to “participate fully in the wellness program” (according to the ACA) to be subject to the standard and any accompanying surcharge. This should include reasonable access to the full range of wellness opportunities provided by the employer. Determinations should err on the side of being protective of dependents.
- To ensure that wellness programs do not violate the Section 2705(j)(3)(B) of the ACA, the regulations should clarify that individuals who receive premium tax credits or cost-sharing assistance cannot be required to spend a greater share of their incomes on premiums or a higher amount on cost-sharing than is permitted for their specific income levels under Sections 1401 and 1402, including the costs of wellness incentives. The regulations should include examples of wellness incentives that would increase enrollees’ premium or cost-sharing amounts beyond their affordability thresholds under Sections 1401 and 1402 to further clarify that such incentives are not permitted.
- Regulations should prohibit wellness incentives that would bring the cost of enrollees’ coverage above the affordability threshold (8 percent of household income) in Section 1501 of the ACA, or otherwise qualify them for a hardship exemption from the individual responsibility requirements. Consideration and protections should be given to confidentiality of employee household income.
- Regulations further should clarify that no enrollee in an employer-sponsored health plan can be required to spend more than the amount deemed affordable for a worker’s share of employer-sponsored coverage (9.5 percent of household income) in Section 1401 of the ACA due to wellness program incentives. The regulations should prohibit wellness incentives that increase employees’ share of premiums above 9.5 percent of their household income.

Enforcement

Employers should be assessed a penalty if wellness adjustments result in workers qualifying for exchange subsidies. Employees should be properly notified of their rights and obligations under such programs; the Department should provide model language for employers to use.

Compliance/Reporting Standards

For employers who claim the wellness exception to the HIPAA nondiscrimination rules, the Departments should require them to report the following every three years:

- Demographic information about employees who decline to participate in the wellness plan;
- The value of the incentives used in the wellness plan and whether they are administered as rewards or penalties, a description of wellness supports and services offered to employees and their cost to the employer;
- The amount of savings to the employer resulting from the wellness plan;
- The impact on premiums due to the wellness plan;
- The amount of insurance costs shifted from the employer to employees due to the wellness plan;
- The documented effect of the wellness plan on employee health status;
- Evidence of employee satisfaction or dissatisfaction with the wellness plan; and

- Assurances that the wellness plan has not resulted in discrimination under Title VII of the Civil Rights Act, the Age Discrimination in Employment Act, the Americans with Disabilities Act, the Genetic Information and Nondiscrimination Act, the Family Medical Leave Act, and Section 1557 of the ACA, or any other Federal or State civil rights law.

Increase of Allowable Cost Variation to 50 percent

We have serious concerns about the proposal to allow cost variations of 50 percent.

First, there needs to be clear guidance on how premiums are determined for plans with wellness program discounts and surcharges because there may be a significant difference between a pool without a wellness program versus one with it. The concern is whether an insurer's initial calculation of the premium includes an adjustment for the expected health benefit of the wellness program or is based on the health of the whole risk pool prior to any implementation of a wellness program. If the community health rating is based on current population health, then the insurer will realize 20 (or 30) percent increase in revenue (i.e., profit) on those not participating in the wellness program because their poor health status was already accounted for in the initial premium calculation. In essence, their "poor health" status is being double counted under this scenario. The question then become what happens to this 20 to 30 percent increase in revenue – how is it accounted for and how is that incorporated into the medical loss ratio?

Second, we are concerned about the effect that an increase to 50 percent would have on affordability and access to care for individuals with pre-existing health conditions or disabilities. We strongly urge the Departments to defer any decision about whether to increase the limit to 50 percent until the completion of a report required in section 2705 within three years of enactment of the ACA. The report must describe:

- The effectiveness of wellness programs;
- The impact of such wellness programs on the access to care and affordability of coverage for participants and non-participants of such programs;
- The impact of premium-based and cost sharing incentives on participant behavior and the role of such programs in changing behavior; and,
- The effectiveness of different types of rewards.

We further urge the Departments to consult with both employers and employees in preparing this report, and to rely on objective, independent evaluations of worksite wellness programs.

After the report is available, we believe the percentage should be increased to 50 percent only when the program employs activities, supports, and services that are recommended by a strong, extensive evidence base; when the participants' insurance plan provides coverage for all evidence-based wellness benefits with no cost-sharing; and when there is empirical evidence that an incentive larger than 30 percent of the cost of employee health care coverage will clearly improve the health outcomes of employees enrolled in the program while not diminishing access to care for any employees.

In closing, we thank you for this opportunity to comment on revised workplace wellness regulations. We believe that the proliferation in the number and type of wellness programs since 2006 and, most importantly, the need to assure that these programs do not undermine the fundamental protections of the ACA, makes a review of these regulations both timely and necessary. A new analysis issued by the Department of Health and Human Services “*At Risk: Pre-Existing Conditions Could Affect 1 in 2 Americans*”²⁴, underscores this point. The report found that as many as half of all non-elderly Americans (129 million) have medical problems that are “red flags” for health insurers and the highest rates can be found among those with employer-sponsored insurance. These red flags included hypertension, high cholesterol, obesity, and high blood glucose (diabetes) – the very same health conditions employees may be penalized for by an employer wellness programs. To protect access and affordability of coverage for individuals with preexisting health conditions or disabilities, which is a cornerstone of the ACA, we urge you to consider the recommendations we have made in this letter.

If you have any questions or need any additional information, please do not hesitate to contact Sue Nelson, Vice President of Federal Advocacy, American Heart Association, at 202-785-7912 or sue.nelson@heart.org.

American Association of People with Disabilities (AAPD)

American Cancer Society – Cancer Action Network

American Diabetes Association

American Federation of Labor and Congress of Industrial Organizations (AFLCIO)

American Federation of State, County and Municipal Employees (AFSCME)

American Heart Association/American Stroke Association

American Society for Metabolic and Bariatric Surgery

The Epilepsy Foundation

Families USA

Health Care for America Now

International Union, United Automobile, Aerospace & Agricultural Implement Workers of America, (UAW)

²⁴ *Ibid.*

National Council of La Raza (NCLR)

National Multiple Sclerosis Society

National Partnership for Women & Families

National Women's Law Center

Obesity Action Coalition

The Obesity Society

Service Employees International Union (SEIU)