A REVIEW OF THE NEW WELLNESS REGULATIONS:

A Departure from Personal Responsibility & Accountability for Health

By Lisa M. Holland, RN, MBA and Gregory J. Hummer, MD

On May 29, the U.S. Departments of the Treasury, Labor (DOL) and Health and Human Services issued the final new wellness regulations which amended the 2006 HIPAA nondiscrimination wellness regulations. The new regulations clarify wellness program categories and clearly define and elaborate on a "Reasonable Alternative" and its application in a Health Contingent model.

The Department has categorized wellness plans into two main categories; **Participatory** and **Health Contingent** plans. Health Contingent plans are further categorized into two distinct subcategories: **Activity Based** and **Outcomes Based** plans. These changes in definitions may place some employer current **Participation** plans into an **Activity** category in 2014 which will require reasonable alternatives, certain disclosure language and increased administrative cost. Due to these changes it is very important that employers begin working with their wellness program vendors or internal legal departments to review the new regulations against current practice in order to ensure compliance in 2014.

The amended regulations now apply to Self Funded Group Health Plans, Fully Insured Plans and Individual Group Health Plans. The Wellness Plan must be part of the Group Health Plan and must be stated so in the complete plan documents and summary plan documents. As such, the law reinforces and modifies the loop hole in the HIPAA non-discrimination rules and mirrors the PHS Act section 2705 that allow a Wellness Plan to "discriminate" or reward a participant based upon a health factor when all of the wellness rules and regulations are properly administered by the plan. Under the amended rules the following plans are defined:

Participatory - a wellness plan that is voluntary, offered to all similar participants and may or may not have an award and the award is not dependant on achieving **any** standard or measurement. If you participate, you qualify for the award. An example is an HRA that is offered, taken by the participant BUT then no further action is required based upon the results of the HRA.

Activity – a wellness plan that is voluntary, offered to all similar participants and requires completion of an "Activity" to get the reward. An example would be: if upon completion of a HRA then an "Activity" is required like a smoking cessation program or weight loss program based upon the results of the HRA or any type of screening or risk factor determination THEN this becomes an "Activity" Based plan and now must have "reasonable" alternative(s) offered. "Specifically, for activity-only wellness programs, a reasonable alternative standard for obtaining the reward must be provided for any individual for whom, for that period, it is either unreasonably difficult due to a medical condition to meet the otherwise applicable standard, or for whom it is medically inadvisable in an attempt to satisfy the otherwise applicable standard."

Outcomes - a wellness plan that is voluntary, offered to all similar participants and has an award dependent upon a participant meeting a health factor such as achieving a BMI of 25. If the HRA or any other type of screening procedure or risk evaluation then requires the participant to meet a standard of measurement like a specific cholesterol level or BMI then this plan is determined to be an "Outcomes" Based program and must offer reasonable alternative(s) as follows: "A reasonable alternative standard or waiver of the standard must be provided to all individuals who do not meet the initial standard, to ensure that the program is reasonably designed to improve health and is not a subterfuge for underwriting or reducing benefits based on health status.''

Reasonable Alternative(s) must be offered at reasonable times and have to be supplied at no cost to the participant except if a diet, the food costs are not covered by the Wellness Plan but all other memberships or other administrative costs have to be paid by the Wellness Plan. It could be possible that a personal physician recommends a fitness center as a reasonable alternative to achieving a BMI of 26. It might be possible under the new regulations that the employer might have to pay for the fitness center membership. Reasonable Alternatives can be determined by the participant and/or in cooperation with the participant's personal physician.

According to the amended wellness regulations ANY plan that is determined to be a Health Contingent program (Activity or Outcomes Based) **MUST** meet the following five (5) conditions:

1. The program must give eligible individuals an opportunity to qualify for the reward at least once per year.

2. The reward for a health-contingent wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, *must not exceed 30 percent of the total cost of employee-only coverage under the plan, or 50 percent to the extent the program is designed to prevent or reduce tobacco use.*

3. The reward must be available to all similarly situated individuals. For this purpose, a reasonable alternative standard (or waiver of the otherwise applicable standard) must be made available to any individual for whom, during that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard (or for whom it is medically inadvisable to attempt to satisfy the otherwise applicable standard).

4. The program must be reasonably designed to promote health or prevent disease. For this purpose, it must have a reasonable chance of improving the health of, or preventing disease in, participating individuals, and not be overly burdensome, not be a subterfuge for discriminating based on a health factor, and not be highly suspect in the method chosen to promote health or prevent disease. The proposed regulations also stated that, to the extent a plan's initial standard for obtaining a reward (or a portion of a reward) is based on results of a measurement, test, or screening that is related to a health factor (such as a biometric examination or a health risk assessment), the plan is not reasonably designed unless it makes available to all individuals who do not meet the standard based on the measurement, test, or screening, a different, reasonable means of qualifying for the reward.

5. The plan must disclose in all plan materials describing the terms of the program the availability of other means of qualifying for the reward or the possibility of waiver of the otherwise applicable standard.

Employers should keep in mind that the intent of the amended wellness regulations,(as actually written in the regulations) is to make sure that no person is discriminated against because of a health factor AND that ALL participants should be able to qualify for the reward even if they do not participate in the Wellness Plan's initial activity OR achieve the initial standard in an Outcomes Based program.

Participants qualify just by doing a reasonable alternative; which said reasonable alternative may be created or determined by the participant or their personal physician. The reasonable alternative offered by the Wellness Plan can be circumvented by invoking their right to have their personal physician design and suggest the alternative. Any plan that falls into the Health Contingent category MUST inform ALL participants through all plan communications and the

actual Health Plan document that the participant can have an alternative and that they can invoke the help of their personal physician to design an alternative.

The very nature of the definitions now allow the participant the opportunity to create "alternatives" upon "alternatives" such that the participant is NOT required to **ever** achieve the initial standard like a normal BMI. In an Outcomes Based program upon NOT receiving the award or getting the penalty the participant must be informed that they failed to achieve the initial standard and perform the alternative.

In an Activity based program, the employer/wellness plan MAY seek written documentation from a personal physician stating that the participant cannot meet the standard for any reason. The participant themselves can determine that they want a reasonable alternative and may also invoke the help of their personal physician should the employer/wellness plan request verification of the waiver for reasonable alternatives. (See page 72 of the new rules)

Whereas, an Outcomes Based program the employer/wellness plan may not seek verification from the participant personal physician stating the reason that they cannot meet the standard. (See page 77 of the new rules). Examples of reasonable alternatives may be found on pages 67-81 of the regulations depicting the types of wellness plan activities and measurements that constitute a Participatory, Activity or Outcomes Based program.

The thinking of the framers of this legislation assume that most participants are truly concerned about their poor health habits and want to change them and that the vast majority of employers will offer plans that have a positive effect on participant's health. However, data over the last 10-15 years shows conclusively that although Americans may want to change their poor health habits, they do not. The advent of the 2008 wellness regulations allowed employers to use preventive practice (worksite wellness programs) as a powerful tool to help employees become responsible and accountable for their health. The amended regulations may have a negative impact on the "growth" and positive impact of employer sponsored "Health Contingent" workplace wellness programs in that they usurp, via personalized alternatives, the very goals that the wellness program has set out to achieve.

Based on the new regulations, employers should continue their worksite wellness efforts. However, we recommend a simple and focused approach that applies a hybrid plan using participation and activity based programs to address the four critical factors that drive 75% of today's chronic disease and healthcare costs. It may also be necessary for employers to amend their group plan summary to say that: Any consultation, office visit, labs or x-rays or procedures incurred by the participant when seeking an alternative to a wellness standard from their medical provider(s) or medical provider treatments, supplies, devices or direct provider services associated with this alternative visit are non-covered services. In addition, employers should couple their wellness program with a higher risk sharing benefit design that includes higher deductibles and consumer driven plans.

In our experience, healthcare affordability will be achieved through the application of personal economics, which will drive most all Americans to change their health behavior. Personal economics can be achieved by implementing tools and resources in the worksite that motivate change by increasing value in an individual's economic future via Health Savings Accounts and Defined Contribution Plans (Financial Wellness), which are facilitated by obtaining a better state of health.

The changes in the final regulations serve to obfuscate the ability of employers to change their participants health habits through personal economics, add more administrative costs to achieve the same dismal results and may lead to the rise of "Wellness Alternative Doctor Mills."

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