Agencies Issue Final Regulations for Nondiscriminatory Wellness Programs

June 12, 2013

On May 29, 2013, the Department of Labor (DOL), Department of Health and Human Services (DHHS) and the Department of the Treasury (IRS) (collectively, Agencies) issued final regulations addressing the implementation of employer-sponsored wellness programs that would not violate the HIPAA prohibitions against discrimination on the basis of health factors (Final Regulations). The Final Regulations were published in the Federal Register (78 FR 33158) on June 3, 2013. These Final Regulations update, revise and reorder the proposed regulations that were issued on November 20, 2012 (Proposed Regulations). See, the Honigman Health Care Reform Alert, January 7, 2013. The proposed regulations had, in turn, built upon the regulations that created a “wellness plan” safe harbor from the HIPAA nondiscrimination requirements issued on December 13, 2006 at 71 FR 75014 (2006 Regulations).

Effective Date and Applicability Date for the Final Regulations – The Final Regulations become effective on August 2, 2013, and will apply to group health plans and group health insurance issuers for plan years beginning on or after January 1, 2014.

Note – The Equal Employment Opportunity Commission (EEOC), which is charged with regulating compliance with the Americans with Disabilities Act (ADA); the Genetic Information Non-Discrimination Act (GINA), the Age Discrimination in Employment Act (ADEA) and the Equal Pay Act (EPA) – all of which have some bearing on wellness programs – has not yet issued any guidance or indicated whether it has signed on to these Final Regulations. The EEOC allows employers to offer non-job-related medical examinations or disability inquiries on a purely voluntary basis, but has not indicated what, if any, level of reward is compatible with a program’s being offered on a “voluntary” basis. A meeting held by the EEOC on May 8, 2013 addressed wellness plan issues, but it does not look like EEOC guidance will be forthcoming any time soon. However, given that these Final Regulations are built on a framework initially articulated in 2006 and the EEOC has not issued any contrary guidance, employers thinking of instituting wellness programs, or who have done so, should pay attention to these Final Regulations and should be able to rely on them going forward.

Two Kinds of Wellness Programs

Under the Final Regulations, as under the Proposed Regulations, there are two kinds of wellness programs – participatory and health-contingent.

Participatory Wellness Program – A participatory wellness program is one that does not provide for rewards or that does not require an individual to satisfy a standard related to a health factor in order to obtain a reward. Examples given are: (i) a program that reimburses employees for all or part of a fitness club membership, (ii) a biometric screening or health risk assessment (HRA) that provides a reward for undergoing the screening or taking the HRA without conditioning the reward in any way on the outcomes, and (iii) a program that rewards employees for attending a monthly, no-cost health education session. Under these Final Regulations, the term “reward” means either obtaining a benefit or avoiding a penalty.

The only requirement for a participatory wellness program is that it must be made available to all similarly situated individuals, regardless of health status. They do not have to meet the five specific criteria that are required of health-contingent wellness programs.
Health-Contingent Wellness Program – A health-contingent wellness program is one that requires an individual to satisfy a health factor-related standard in order to obtain the reward. New under the Final Regulations is the further breakdown of health-contingent wellness programs into (i) activity-only wellness programs and (ii) outcome-based wellness programs.

Clarifying the Distinction between the Two Kinds of Health-Contingent Wellness Programs

Activity-Only Wellness Program – Under an activity-only wellness program, an individual is required to perform or complete an activity related to a health factor in order to obtain the required, but the individual does not have to attain or maintain a specific health outcome to earn the reward. For example, an individual who registers as obese on a BMI screening may earn the reward by participating in a walking or exercise program for a specified period, even if at the end they still test as obese.

Outcome-Based Wellness Program – Under an outcome-based wellness program an individual must attain or maintain a specific health outcome to earn the reward, e.g., quit smoking, score a “non-obese” BMI rating, have a cholesterol reading under 200, etc.

Requirements for Health-Contingent Wellness Programs

Since both of these varieties of wellness programs are “health-contingent,” they must comply with the five criteria required of such programs, but each of the two kinds of health-contingent programs must comply with the criteria somewhat differently. The five criteria are:

• Frequency of Opportunity to Qualify – Individuals eligible for the program must be given an opportunity to obtain the reward at least once a year. This criterion applies equally to both kinds of health-contingent programs.

• Size of the Reward – For both of these programs the available reward cannot exceed 30% of the cost of coverage (employee and employer share) for the option applicable to the employee – i.e., 30% of the cost of employee only coverage, if only employees can be wellness program participants; 30% of the cost of employee plus one coverage, if spouses are allowed to participate and such an option is available; or 30% of the cost of family coverage, if spouses or all family members are allowed to participate. In addition, the reward can increase 20% (i.e., to 50%), if the additional percentage is in connection with a program designed to reduce or eliminate tobacco use. Thus, a 10% reward for a specific biometric screening result and 40% reward for a smoking cessation program passes muster, as would a 50% reward for a smoking cessation program with no reward for biometric screening results, but not a 30% reward for a biometric screening result and a 50% reward in connection with a tobacco use program. The 30% reward level is an increase from the 20% level under the Proposed Rules, as is the additional 20% tobacco use reward.

• Reasonable Design – As in the Proposed Rule, a program meets this standard, if (i) it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, (ii) it is not overly burdensome, (iii) it is not a subterfuge for discriminating based on a health factor and (iv) it is not highly suspect in the method chosen to promote health or prevent disease. This determination will be based on all the relevant facts and circumstances. This criterion applies to both kinds of health-contingent programs.
• **Uniform Availability and Reasonable Alternative Standards** – The full reward must be available to all similarly situated individuals, though there is some flexibility in making the determination as to which individuals are “similarly situated.” Programs or rewards can differ for participants in different benefit options (e.g., PPO versus HMO), different dependent groups (e.g., spouses versus children), and different *bona fide* employment-related classifications (e.g., hourly versus salary, union versus non-union, different business units, different geographical locations, *etc.*). This is also true for both kinds of health-contingent programs.

The Final Regulations emphasize that for health-contingent wellness programs, one way to comply with this requirement is with respect to specific individuals or groups of individuals to simply waive the requirement to meet the health factor standard and for the individual(s) to earn the reward. While in certain situations that might be a reasonable alternative, but if this waiver option becomes the norm it makes a health-contingent program hard, if not impossible, to distinguish from a participatory program.

Assuming then, that the employer wishes to maintain a health-contingent program and wants to provide a meaningful alternative standard, here is where the requirements under each of the two varieties of health-contingent programs differ.

1. **Activity-Only Wellness Programs** – For an activity-only wellness program to be deemed as being available to all similarly situated individuals, it must (i) allow a reasonable alternative standard for obtaining the reward to be available to all, and (ii) an alternative to the reasonable alternative standard must be available for those for whom it is medically inadvisable to try to satisfy the reasonable alternative standard.

In this latter case, plans may seek verification or certification from a participant’s physician that the individual’s seeking to comply with the plan’s reasonable alternative standard is medically inadvisable and an alternative to the plan’s proffered alternative must be provided. This “alternative,” so to speak, can be tailored to the individual and can be agreed upon at the time the individual indicates that such an alternative is needed.

Whether an individual is entitled to an alternative to the reasonable alternative standard due to medical inadvisability is a decision that is deemed to involve medical judgment, and is, therefore, eligible for external review under the Affordable Care Act’s Federal external review procedures.

2. **Outcome-Based Wellness Programs** – For an outcome-based wellness program to be deemed as being available to all similarly situated individuals, it must allow (i) a reasonable alternative standard for obtaining the reward to be available to all, (ii) the alternative standard must be made available at the individual’s request, (iii) if the alternative standard is itself an activity-based standard, it must meet the requirements for activity based wellness program standards as if it were the initial program standard, (iv) the reasonable alternative standard cannot be a requirement to meet a different level of the same standard without additional time to comply that takes into account the individual’s circumstances, and (v) the plan cannot request verification or certification from an individual’s physician, but the individual must be given an opportunity to comply with a course of action recommended by the individual’s physician as an alternative means of obtaining the reward – as opposed to meeting the reasonable alternative
standard defined by the plan – but only if the physician joins in the request.

3. **For Both Kinds of Health-Contingent Wellness Programs** – All the facts and circumstances will be taken into account in determining whether a plan has furnished a reasonable alternative standard, included, but not limited to the following:

- If the alternative standard is an education program, it must be made available to the individual for free, or the plan must assist the employee in finding such a program and pay for the cost of the program.

- The time commitment required must be reasonable *(e.g., nightly attendance at a one-hour class would not be reasonable)*. This is new under the Final Regulations.

- If the alternative standard is a diet program, the plan must pay the membership or participation fee, but not the cost of any required foods or supplements.

- If an individual’s physician states that the alternate standard is not medically appropriate, the plan must provide an alternative that accommodates the physician’s recommendations, with standard cost sharing for any items or services required pursuant to the physician’s recommendations.

The Final Regulations are very clear that plans cannot cease to provide a reasonable alternative standard for obtaining a reward under any health-contingent wellness program merely because an individual was not successful in satisfying the initial standard. Rather, the plan must continue to offer a reasonable alternative standard whether the same one or a different one. While this could conceivably lead to an endless repetition of alternative standards to obtain the reward in consecutive years without achieving the desired health outcomes, some of the requirements for outcome-based programs (specifically, the requirements in Section 4.B (iv) and (v)) are expressly intended to “prevent a never-ending cycle of reasonable alternative standards being required by plans.” It remains to be seen whether these requirements will prove successful.

- **Notice of Availability of Reasonable Alternative Standard** – All plan materials describing the terms of a health-contingent wellness program, the terms of such programs and the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of a waiver of such standard). For outcome-based wellness programs, this disclosure must also be made in any communication that an individual failed to satisfy the initial outcome-based standard for earning the reward. The disclosure must also include contact information for obtaining a reasonable alternative standard and a statement that the recommendations of an individual’s personal physician will be accommodated. The Final Regulations provide sample language that can be used to meet this disclosure obligation.

**Action Steps**
If you are planning to implement a wellness program or have implemented a wellness program and need to consider how it might need to be modified under these Final Regulations, or if you have any other Affordable Care Act compliance issues, or issues concerning any other employee benefit matter, please contact one of the Employee Benefits attorneys.