Final Wellness Regulations Create New Program Categories and Complications

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The Departments of Labor, Treasury, and Health and Human Services (the Departments) recently published final Affordable Care Act (ACA) regulations on wellness programs, effective in 2014. The regulations retain the existing distinction between participatory and health-contingent wellness programs, but clarify that many wellness programs have been incorrectly classified as participatory. The regulations also split health-contingent wellness programs into two subcategories subject to new requirements. While reviewing programs for consistency with these regulations, plans must simultaneously track Equal Employment Opportunity Commission (EEOC) and state regulatory efforts.

Right now, health care cost containment is a top priority for employers, employees, and the Departments. In this environment, attention has inevitably turned to employer wellness programs and their potential for improving employee health, reducing long-term costs, and providing immediate returns on investment. A recent RAND Corporation[1] report confirms this trend, finding that more than 60 percent of employers with 100 or more employees sponsor a wellness program.

Wellness programs must comply with a variety of federal laws. Chief among these is the Health Insurance Portability and Accountability Act (HIPAA), which established wellness programs as an exception to the general rule that a group health plan's terms of coverage may not vary based on participants' health. The ACA expanded upon the HIPAA nondiscrimination rules and wellness exemption. The Departments' new wellness regulations reflect these ACA updates and lay out specific wellness program requirements for all plan years starting on or after January 1, 2014.

Wellness Program Incentives and Pay-or-Play

Many wellness programs provide rewards or impose surcharges on health plan participants in order to incentivize improved health habits. Under the final regulations, these rewards (or surcharges) can take the form of cash, gift cards, or adjustments to a participant's health plan costs (for example, premium or deductible reductions, or copayment waivers).

Although wellness programs directly affect the actual cost of health care for many employees, wellness rewards (and surcharges) will generally be disregarded in determining

affordability and minimum value under the employer's health plan for purposes of the shared responsibility (that is, "pay-or-play") rules under Section 4980H(b) of the Internal Revenue Code of 1986, as amended. In separate regulations, the Department of the Treasury has proposed a lone exception, under which tobacco-related wellness rewards will be presumed earned for affordability and minimum value calculations.

Participatory Wellness Programs

Definition

A wellness program is participatory if it either offers no reward or conditions rewards only on activities unrelated to any health factor. Examples of health factors are health status, medical condition, genetic information, and disability. An activity relates to a health factor if an adverse health factor could frustrate efforts to complete the activity. For example, a $300 reward for purchasing a treadmill is a participatory program, but a $300 reward for regularly walking on a treadmill as part of a fitness program is not. No health factor precludes buying fitness products, but many health factors (for example, asthma) might frustrate efforts to participate in a walking program.

Examples of participatory wellness programs include programs that reward completion of a health risk assessment, attending a health education class, or pursuing certain medical care (for example, prenatal care). Programs often mistakenly identified as participatory include programs that offer rewards for completing exercise or diet regimens.

Requirements

The only regulatory mandate for participatory wellness programs is that they must be offered to all similarly situated individuals. Accordingly, all employees must generally be offered the opportunity to participate in a participatory wellness program, unless a *bona fide* employment-based classification (for example, full-time versus part-time or office location) dictates otherwise. An exception to this rule is that wellness programs designed for the benefit of individuals with an adverse health factor (for example, a disease management program for diabetes) may limit enrollment to individuals possessing that adverse health factor.

Health-Contingent Wellness Programs

Definition

Any wellness program that is not participatory is considered health-contingent. The final regulations classify all health-contingent wellness programs into two new subcategories: activity-only and outcome-based. Activity-only wellness programs condition all rewards on merely participating in an activity related to a health factor and do not require participants to achieve any specific health outcome. Examples include participation in a diet program or exercise program. Outcome-based wellness programs condition rewards on attaining or maintaining a specific, measured health outcome. Examples include achieving a body mass index (BMI) or blood pressure level within a specified range or abstaining from smoking. Informally, the Department of Labor has indicated that if a wellness program allows for a reward to be earned by either completing an activity-only requirement or achieving an outcome-based goal (for example, $100 for either completing a diet program or registering a healthy BMI level), the program will be considered outcome-based.

Requirements

Both activity-only and outcome-based wellness programs are subject to the same five requirements, listed below. However, important differences exist in application of the fifth requirement, the "reasonable alternative" requirement.

1. Eligible individuals must have an opportunity to earn all health-contingent rewards at least once each year. If a program offers multiple opportunities to earn the reward (pursuant to the reasonable alternative requirement discussed below), all participants must be provided the same reward amount, even if they earn the reward at different times. This may require crediting rewards retroactively.

2. The total rewards available under all health-contingent programs (other than tobacco-cessation programs) must not exceed 30 percent of health plan coverage costs. If a plan offers tobacco-cessation rewards, those rewards may add an additional 20 percent, increasing the total reward limit to 50 percent.

Generally, the reward limit is calculated as a percentage of the total (employer plus employee) premiums for employee-only health plan coverage. But, if any covered dependents are eligible for health-contingent wellness rewards, then the reward limit is calculated as a percentage of the total premiums for the applicable coverage level, whether family coverage or spousal coverage. The plan sponsor can choose to grant rewards on an all-or-nothing

basis (for example, an entire family must complete the wellness program to earn any reward) or a *pro rata* basis (for example, 80 percent of the reward will be granted if 80 percent of eligible family members complete program).

3. Health-contingent programs must be reasonably designed to promote health or prevent disease, not be overly burdensome, not be a subterfuge for discrimination based on a health factor, and not be highly suspect in the method chosen to promote health or prevent disease. A wellness program need not have clinical evidence of its efficacy, although the Departments note that basing a wellness program on evidence-based studies is a best practice.

4. Plan materials that describe the manner in which a health-contingent reward is earned must also note the availability of a reasonable alternative means of qualifying for the reward. The regulations include sample disclosure language.

5. All similarly situated individuals must have an opportunity to earn a health-contingent reward. This requirement has been revised since the proposed regulations and is now tailored to the two different health-contingent subcategories, as explained in the following section.

Reasonable Alternative Requirement for Healt-hcontinegent Programs

Activity-Based Health-Contingent Programs

Activity-based wellness programs must offer either a waiver or a reasonable alternative to the initial reward standard if a participant's medical condition makes it unreasonably difficult or medically inadvisable to satisfy that initial standard. If a participant requests a reasonable alternative, the plan sponsor can request verification of the participant's medical impediment from that participant's physician (or whichever practitioner the plan deems appropriate), as long as the verification request is reasonable. A request for verification is always reasonable if medical judgment is involved in determining whether the participant's medical condition makes the program's initial standard unreasonably difficult or inadvisable.

Reasonable alternatives can be standardized or determined on a case-by-case basis, but can never subject the affected participant to additional costs or unreasonable time commitments. If a reasonable alternative is unreasonably difficult or medically inadvisable for the participant, then the alternative must be revised to satisfy the concerns of the participant's physician or another reasonable alternative must be offered.

Outcome-Based Health-Contingent Programs

Outcome-based wellness programs must offer a waiver or a reasonable alternative to *every* participant who does not meet the initial standard. The reasonable alternative requirement for outcome-based programs is not contingent on the existence of any medical condition that frustrates the participant's efforts, so requests for physician verification are not permitted. Whenever a participant fails to meet the initial standard of an outcome-based program, the plan sponsor can choose between offering an activity-based reasonable alternative or another outcome-based reasonable alternative.

When an activity-based reasonable alternative is offered under a plan (for example, an exercise program is offered as an alternative to an initial standard of registering a BMI under 30), the offer is subject to the reasonable alternative requirements applicable to activity-based programs described above, including the requirement to offer further reasonable alternatives (for example, a diet program) if a medical condition makes it unreasonably difficult or medically inadvisable to satisfy the first activity-based alternative (the exercise program) offered.

When an outcome-based reasonable alternative is offered under a plan, it must provide the participant with a reasonable time frame to achieve the standard (for example, reduce BMI by 5 percent in six months as an alternative to aninitial standard of registering a BMI under 30). If the reasonable alternative offered is outcome-based, the offer must also include the opportunity for the participant's physician to design a different reasonable alternative.

Prospects for EEOC Harmonization with the Departments

The EEOC has regulatory oversight over wellness programs through its enforcement of the Americans with Disabilities Act (ADA) and the Genetic Information Nondiscrimination Act (GINA). These laws' prohibitions on disability and genetic information-related inquiries implicate many wellness programs, including popular health risk assessments. At a recent public hearing on wellness,

EEOC Commissioner Lipnic[2] indicated that clarity on compliance requirements may be forthcoming, stating "I believe we have a responsibility where possible to let stakeholders know the [EEOC's] position on these important questions." However, when EEOC guidance is eventually promulgated, there is no assurance that the EEOC's approach will be consistent with the Departments' final regulations.

State Regulation of Wellness Programs

In addition to federal regulation, wellness programs may be subject to a patchwork of state laws. A common approach to reducing potential conflicts with these state regulations is to integrate wellness programs into an Employee Retirement Income Security Act (ERISA) group "wrap" health and welfare plan. If a wellness program is part of an ERISA employee benefit plan, ERISA preemption will excuse the wellness program from compliance with many state regulations.

Establishing a wellness program as part of an ERISA benefits plan cannot single-handedly resolve all state law conflicts, however. State insurance laws are excepted from ERISA preemption. For employers with fully insured health plans, it is important to open a dialogue among their benefits counsel, health insurer(s), and wellness program vendor(s) to identify any conflicting state insurance laws and all potential in-plan or extra-plan workarounds. Among the state insurance laws that can affect wellness initiatives at employers with fully insured health plans are the following:

- Prohibitions on health-contingent wellness programs (Cal. Senate Bill 189);
- Reduced limits on healthcontingent wellness incentives; (Va. Code Ann. § 38.2-3454(B) (1) (not authorizing the ACA tobacco-related incentives in excess of 30 percent));
- Prohibitions on health-contingent incentives structured as surcharges or penalties (Md. Code Ann., Ins. § 15-509(b)(1)(ii));
- Restrictions on the form of wellness incentives (N.Y. Ins. Law § 3239(c) (2013) (restricting wellness rewards structured as premium reductions), or Cal. Senate Bill 189 (barring cost-sharing rewards in participatory wellness programs)); and
- Prohibitions on rebating health insurance premiums (D.C. Code § 31-2231.12(a)(2)(A)).

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Endnotes

1 RAND Corp., Workplace Wellness Program Study: Final Report, 19 (2013), available at *http://www.rand.org/pubs/research_reports.html*.

2 Press Release, EEOC, Employer Wellness Programs Need Guidance to Avoid Discrimination (May 8, 2013).

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