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DOL, TREASURY & HHS ISSUE FINAL WELLNESS PROGRAM RULES

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On December 13, 2006, the Departments of Labor, Treasury, and Health and Human Services (the "Departments") issued final HIPAA nondiscrimination and wellness program regulations. 71 Fed. Reg. 75014. The Departments had issued interim final nondiscrimination rules and proposed bona fide wellness program rules in 2001. 66 Fed. Reg. 1378 (Jan. 8, 2001) (nondiscrimination); 66 Fed. Reg. 1421 (Jan. 8, 2001) (wellness). The new rules apply to "group health plans" under HIPAA and are applicable to plan years beginning on or after July 1, 2007 (January 1, 2008 for calendar year plans).

The final wellness program rules retain the same overall structure of the proposed rules, but add an additional factor that wellness programs must meet to be permissible, add more examples to demonstrate programs that meet the requirements, and clarify when a program is subject to these rules. The new rules also drop the term "bona fide" and simply refer to these arrangements as "wellness programs." In addition, the Departments say that, while they had taken a nonenforcement approach until additional guidance could be issued, this nonenforcement policy "ends upon the applicability date of these final regulations."

Programs Subject to Wellness Program Rules

The final rules define a wellness program as "any program designed to promote health or prevent disease." The rules say that a plan must meet these wellness program requirements if it varies benefits, premiums, or contributions for similarly situated individuals in connection with a wellness program.

However, the Departments clarify that in order to be subject to these rules, a program must be based on an individual satisfying a standard related to a health factor to obtain a reward. If none of the conditions for obtaining a reward is based on an individual satisfying a health-related standard (for example, the program is measured merely by participation), the program would not be subject to these rules.

The regulations give several examples of programs that would not be based on a health factor, so would not be subject to these rules:

- A program that reimburses cost of membership in a fitness center.
- A diagnostic testing program that provides a reward for participation only, and is not based on any outcomes.

- A program that waives copayments for the cost of prenatal care or well-baby visits in order to encourage preventive care.
- A program that reimburses employees for smoking cessation classes without regard to whether the employee stops smoking.
- A program that rewards employees for attending a monthly health education seminar.

Five New Wellness Program Factors

If an employer's program does offer a reward or penalty based on an employee achieving a health standard, the program must meet the following five requirements:

(1) Amount of Reward - The total reward for the wellness program, coupled with the reward for other wellness programs under the plan, must not exceed 20% of the cost of employee-only coverage under the plan. In proposed regulations, the Departments had offered a range from 10-20% for this limitation, which had caused a great deal of confusion. The Departments settled on 20% and said the limitation is designed to avoid a reward or penalty that is so large that it denies coverage or creates too heavy a financial penalty on individuals who cannot satisfy the wellness program standard.

The final rules state that the cost of employee-only coverage includes both employer and employee contributions with respect to that employee. For example, if the annual premium with respect to Employee X is $3,600, of which the employer pays $2,700 and the employee pays $900, the total health-related rewards under wellness programs for that plan cannot exceed 20% of $3,600 - or $720.

The final rules clarify how this limit should be calculated when a plan offers both individual and family coverage. First of all, the regulations provide that the 20% limit applies to the entire family (so the plan cannot offer 20% per person). In addition, if only the employee is eligible for the wellness program, the 20% limit must be based on the cost of individual coverage (even if the employee has family coverage). If other family members are eligible for the wellness program, the 20% limit should be based on the cost of family coverage.

(2) Reasonableness Standard - The final rules add a somewhat new standard - that a program must be reasonably designed to promote health or prevent disease. Under the proposed rules, this standard had been combined with #3 below, which requires the program to be offered at least once per year. However, the Departments said that other factors could affect the reasonableness of a program, so set these two requirements apart.

The final rules state that a program will be "reasonable" if it has a reasonable chance of improving health or preventing disease, is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not "highly suspect" (*e.g.*, extreme or illegal). In the Preamble, the Departments say this requirement is intended to be "easy" to satisfy and to allow experimentation in diverse ways of promoting wellness.

(3) Opportunity to Qualify Once Per Year - The final rules retain the requirement that the plan must give participants the opportunity to qualify for the reward at least once per year. The Preamble to the proposed rules said that this factor was intended to preclude a plan from basing a participant's reward or premium solely on health factors present when the individual first enrolled.

(4) Reasonable Alternative - The final rules also retain the requirement that the program must allow a "reasonable alternative standard" to any individual for whom it is unreasonably difficult due to a medical condition, or medically inadvisable, to satisfy the otherwise applicable standard. The regulations give the following examples:

- A reasonable alternative to a stop smoking requirement could be to require the employee to attend smoking cessation classes or to view, over a 12-month period, a 12-hour video on the health issues associated with tobacco use.

- A reasonable alternative to a lower cholesterol requirement could be to require an individual to follow his doctor's advice regarding medication and monitoring.

- A reasonable alternative to a lower body mass index requirement could be to require an individual to walk 20 minutes per day, three days a week (the regulations state that if the individual medically cannot meet this alternative, the plan must design another).

As in the proposed rules, the plan does not have to determine the alternative standard ahead of time, but must make one available if an individual requests. New guidance in the final rules says that the plan need not design a specific alternative standard, but simply may say that the alternative is to follow the recommendations of the individual's physician regarding the health factor at issue, or the alternative can be that the plan waives the health standard altogether.

The final rules also clarify that the plan may seek verification, such as a statement from the individual's physician, that the health factor makes it unreasonably difficult or medically inadvisable for the individual to attempt to satisfy the required standard.

(5) Disclosure of Reasonable Alternative - As in the proposed rules, the final rules require the plan to disclose the availability of an alternative standard in all plan materials describing the wellness program (unless the materials merely mention the program, without describing its terms). The regulations provide the following safe harbor language (which is the same as in the proposed rules):

"If it is unreasonably difficult due to a medical condition for you to achieve the standards for the reward under this program, or if it is medically inadvisable for you to attempt to achieve the standards for the reward under this program, call us at [insert telephone number] and we will work with you to develop another way to qualify for the reward."

Examples

The final regulations provide a number of examples of wellness programs that are permissible, including programs imposing a smoker surcharge, a premium discount for participants with cholesterol below a certain level, and a deductible wavier for individuals with a certain body mass index. In the Preamble, the Departments say that these examples serve as safe harbors, so that a plan could be assured of satisfying the wellness program rules if it adopts one of these programs. The Departments say, however, that they do not want plans to feel constrained by the relatively narrow range of programs described in the examples, but to feel free to consider innovative programs to motivate individuals to improve their health.

Other Wellness Program Issues

There are a few questions the Departments left unanswered -

- When an individual cannot medically satisfy the required standard, several wellness programs require an individual to *complete* an alternative program before receiving a reward. Some of these alternative programs can be as long as a year. It is still not clear whether this delayed reward (as opposed to a reward for ongoing participation) would be permissible under the rules.

- A recent trend has been to identify individuals with an adverse health status, such as diabetes or asthma, and invite them to join a disease management program. If the individual refuses, they are assessed a penalty. DOL issued an informal Q&A to the American Bar Association indicating that this type of program is discriminatory, in that only non-healthy individuals are eligible for the penalty, and must comply with the wellness program rules. The final rules do not address these types of programs.

- It is fairly common for plans to offer an incentive, or in some cases a penalty, for individuals to complete a health risk assessment. This appears to be outside of the wellness program rules, in that the reward/penalty is not based on a health factor. However, it still could raise issues under the ADA, which

prohibits an employer from requiring mandatory examinations. This issue is not discussed in the final regulations, but the Departments did point out that the EEOC (which enforces the ADA) asked the Departments to clarify that certain plan practices permitted under the HIPAA rules still may violate the ADA.

In addition, employers designing their wellness programs should keep in mind other issues that may arise. For example, employers should consider whether, and how, to include these programs under an ERISA plan (and whether to offer COBRA, HIPAA certificates of coverage, etc.), how the HIPAA privacy regulations may impact disclosure of information to third parties, and whether rewards under these programs are taxable.

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