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## Agencies Issue New HIPAA Proposed Rule on Wellness Programs

On November 26, 2012, the Departments of Treasury, Labor, and Health and Human Services published a new proposed rule that would change the HIPAA wellness program regulations. 77 Fed. Reg. 70620. The proposed rule would not be binding until issued in final form, but, once issued, is expected to be applicable as of January 1, 2014. Comments are due January 25, 2013.

The HIPAA wellness rules are part of the existing HIPAA nondiscrimination rules. 71 Fed. Reg. 75014 (Dec. 13, 2006). The nondiscrimination rules prohibit a group health plan from discriminating against an individual based on a health factor, except in two circumstances – if the discrimination is in favor of an individual with an adverse health status (called benign discrimination) or if part of a wellness program that meets the requirements of the regulation.

Since publication of the existing wellness rules, the Affordable Care Act (ACA) incorporated many of the regulatory requirements into the HIPAA portability statute and increased the limits for incentives beginning in 2014. In addition, the agencies held hearings with employer and consumer groups regarding comments on the existing rule. The new proposed rule adopts the same general structure as the existing HIPAA wellness rule, but also incorporates the new ACA provisions, as well as other changes

### PARTICIPATION-ONLY PROGRAMS VERSUS HEALTH-BASED PROGRAMS

As under the existing rules, the requirements for health-based wellness programs would not apply to "participatory programs." The proposed rule defines a "participatory program" as a program where none of the conditions for obtaining a reward is based on an individual satisfying a standard related to a health factor or where a program does not provide a reward.

**PRACTICE NOTE:** *Some plans mistakenly add up all wellness program incentives when calculating compliance with the current 20% limit (soon to be 30%), including participation-only incentives. For example, if a plan rewards \$50 for taking a biometric screening and \$25 if the screening shows a favorable BMI, only \$25 must be counted toward the 20% limit.*

The proposed rule provides the following examples of participatory programs:

- A program that reimburses for fitness center costs.

- A diagnostic testing program that provides a reward for participation, rather than outcomes.
- A program that waives copays or deductibles for prenatal care or well-baby visits.
- A program that reimburses costs of participating in smoking cessation, regardless of whether the employee quits smoking.
- A program that rewards employees who complete a health risk assessment, without further action related to health issues identified as part of the health risk assessment.

**NEW!** The proposed rule adds a new requirement that the program also be available to all similarly situated employees. The existing HIPAA nondiscrimination regulations already define "similarly situated" and allow distinctions based on bona fide employment based classifications (such as geographic area or part-time versus full-time) or between employees and dependents.

The wellness program requirements do apply to "health-contingent programs," which are defined as programs where any of the conditions for obtaining a reward is based on an individual satisfying a standard that is related to a health factor. The proposed rule provides the following examples of health-contingent programs:

- A program that imposes a premium surcharge based on tobacco use.
- A two-step program, where step one uses a biometric screening or health risk assessment to identify employees with medical conditions or risk factors (such as high cholesterol, blood pressure, BMI, or glucose level). Step two would require employees identified as at risk to take additional steps, such as meeting with a health coach, taking a fitness course, or complying with a provider's plan of care, to obtain the same reward as healthy employees.

**PRACTICE NOTE:** *Some employers have thought these types of two-step programs could be considered participation only because the individuals identified as at-risk simply had to participate in a coaching program or provider's plan of care, with no further health requirements. However, since the identification of individuals who are at-risk under step 1 is based on a health standard, the agencies consider this type of program to be a health-contingent program.*

#### **FIVE REQUIREMENTS FOR HEALTH-CONTINGENT PROGRAMS**

To meet the wellness program exception, the new proposed rule would require a health-contingent wellness program to meet the following five requirements:

##### **1. Annual Qualification**

As under the existing rules, the program must give individuals the opportunity to qualify at least once per year.

##### **2. 30% Limit on Health-Based Incentives (and up to 50% if Related to Tobacco-Use)**

##### ***Incentive Limit Increased***

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The reward for a health-contingent wellness program, together with the reward for other health-contingent wellness programs under the plan, must not exceed "the applicable percentage" of the cost of employee-only coverage under the plan.

**NEW!** Currently, the HIPAA wellness rules limit the amount of health-based incentives to 20% of the cost of coverage. As mandated by the ACA, the proposed rule adopts a higher limit of 30%, beginning in 2014.

**NEW!** The ACA also gave the Secretary of HHS the discretion to increase the limit to 50%. In somewhat of a surprise move, the proposed rule did increase the limit to 50% for wellness programs that are designed to prevent or reduce tobacco use. Note that the agencies asked for comments on whether there should be a uniform definition of "tobacco use," such as no tobacco use within a certain amount of time or tobacco use that rises to the level of addictive behavior. Since health plans have a variety of ways that they define this standard in current programs, they should keep an eye on possible changes here.

**NEW!** On the same day that the proposed wellness rule was issued, HHS issued a proposed rule on premium rates under the ACA cite. This rule generally allows group insurance rates in the small group market to vary up to 50% based on tobacco use, but then cross-references the wellness rules. The Preamble to the proposed rating rule says this means that a rate increase with respect to tobacco use only would be permitted if in connection with a wellness program that meets the wellness rule, suggesting that individuals would need to be provided a reasonable alternative to avoid the increase in the group rate as well as with respect to their own individual incentive amount. There are a number of questions about how the interaction of these two rules would operate as a practical matter.

#### ***How to Calculate Limit***

As in the current rules, the cost of coverage is based on the total amount of employer plus employee contributions for the benefit package under which the employee is receiving coverage (or the employee and dependents, where applicable). The proposed rule provides an example where the employee portion is \$1,500 and employer portion is \$4,500. The example says that the applicable percentage would be calculated based on the total cost of coverage of \$6,000 (\$1,500+\$4,500). In addition, the cost is based on employee-only coverage unless any class of dependents may participate, in which case the reward may be based on the total cost of the coverage in which the employee and any dependents are enrolled.

**PRACTICE NOTE:** *The mechanics of calculating the incentive limit can be confusing. The percentage limit applies to all health-based wellness programs offered by the group health plan. For example, if a plan has a cholesterol program and diabetes management program, health-based incentives for both programs must be added together to determine compliance with the 20% (or upcoming 30%) limit. If a plan only offers the wellness program to employees (and not dependents), the plan should use the single rate when calculating cost of coverage, even if that particular employee has family coverage. If the plan offers the wellness program to dependents as well, the plan may use the rate for the option in which the employee or dependents are enrolled (single, single plus one, family, etc.).*

**NEW!** If the plan wants to use the new 50% limit for tobacco use, it may need to test incentives for tobacco programs and non-tobacco programs separately. For example, if a wellness program is only based on tobacco use, the incentive may be up to 50% of the cost of coverage. However if the wellness program is based on both tobacco use and other health-contingent factors (such as cholesterol or blood sugar), the incentives not related to tobacco are still capped at 30% of the cost of coverage, but the incentive related to tobacco use may go up to 50% of the cost of coverage.

### 3. Reasonable Alternative

As under the current rules, the program must provide a "reasonable alternative" to the health-based standard, or waive the health-based standard, to earn the same reward for individuals for whom it is unreasonably difficult or medically inadvisable to meet initial standard. The plan is not required to determine the reasonable alternative in advance, but must provide one if an individual requests.

**NEW!** The proposed rule provides that whether a standard is reasonable will depend on facts and circumstances and also provides some guidelines:

- If the reasonable alternative is completion of an educational program, the plan must make the program available and not require an individual to find a program unassisted. The plan also may not require the individual to pay for the program.
- If the reasonable alternative is a diet program, the plan must pay any membership or participation fee, but is not required to pay the cost of food.
- If the reasonable alternative is compliance with the recommendations of a medical professional engaged by the plan, and an individual's personal physician believes that these recommendations are not medically appropriate, the plan must provide another reasonable alternative that accommodates the personal physician's recommendations. The plan may impose standard cost sharing for medical items and services furnished pursuant to the physician's recommendations.

As in the existing rules, a plan may seek verification, such as a physician's statement, that it is unreasonably difficult or medically inadvisable for the individual to meet initial standard, so the individual should be given the reasonable alternative.

**New!** The proposed rule adds a requirement that a plan only may seek physician verification "if reasonable under the circumstances" and says that it would not be reasonable for a plan to seek verification of a claim that is "obviously valid based on information known" to the plan. It is unclear how this new standard would be applied. Arguably a health plan may have access to all of an individual's health and claims records so may never need a physician's verification of a condition. But these records are typically housed with a variety of insurers or claims administrators, who may be reluctant to hand them over to the employer administering the wellness program due to HIPAA privacy concerns. Also, plans typically do not want to be seen as "second-guessing" an individual's doctor, so they routinely ask for this type of verification so they aren't the party making a medical judgment decision (an even more important consideration now that these medical judgment decisions may be subject to external review). This is an area to watch.

### 4. Reasonable Design

A wellness program must be reasonably designed to promote health or prevent disease. As under the current rules, the proposed rule provides that a program will meet this standard 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 in the method chosen to promote health or prevent disease.

**NEW!** The proposed rule adds that this determination is based on all the relevant facts and circumstances. Thus, it is not clear how "customized" a program must be in order to be considered reasonable. Also, the agencies ask whether there should be other standards to determine reasonableness, such as evidence- or practice-based standards.

**NEW!** The proposed rule also adds a new requirement that if the standard for obtaining a reward is based on a measurement, screening, or test relating to a health factor, such as in a health risk assessment or biometric screening, the program must make available a "different reasonable means of qualifying for the reward" for any individual who does not meet standard. Aside from the 50% incentive limit for tobacco use, this is probably the most significant change to these proposed rules. This requirement to offer a "different" means of qualifying for the reward would be in addition to the reasonable alternative above for those who cannot medically meet the required standard. This new rule essentially would expand the "reasonable alternative" requirement to all participants, regardless of their medical situation.

## **5. Notice of Other Means to Qualify**

The plan must disclose in all plan materials describing the program the availability of "other means of qualifying for the reward" or the possibility of a waiver of the otherwise applicable standard. The existing rule required a similar notice with respect to the reasonable alternative standard. The Preamble provides that if plan materials merely mention that a program is available, without describing the terms, the disclosure is not required. The Preamble also states that the notice would not need to be included in the new Summaries of Benefits and Coverage (SBCs) required under the ACA.

**NEW!** The proposed rule updates the sample language for this notice to read:

"Your health plan is committed to helping you achieve your best health status. Rewards for participating in a wellness program are available to all employees. If you think you might be unable to meet a standard for a reward under this wellness program, you might qualify for an opportunity to earn the same reward by different means. Contact us at [inset contact number] and we will work with you to find a wellness program with the same reward that is right for you in light of your health status."

The proposed rule also provides examples where the plan customizes this language to address a particular health standard.

## **SCOPE OF RULE**

The HIPAA wellness rules apply to group health plans and health insurance issuers offering coverage to group health plans. There had been some question about how the ACA changes, particularly the increased incentive limit, might apply to grandfathered plans under the ACA, since the ACA generally excepted this group from the section that included wellness. The agencies classified that the proposed rules would apply to both grandfathered and non-grandfathered plans.

For individual coverage, the proposed rule provides that an issuer in the individual market is subject to the nondiscrimination rules to the same extent as an issuer in the group market. The Preamble notes that the wellness exception, however, does not extend to the individual market. 77 Fed. Reg. 70625.

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At first glance, it may appear that the proposed rule is very similar to the existing wellness rule. However, as discussed above, there are a number of changes that could have a significant impact on how wellness programs are designed and administered, particularly the new limits, the restrictions around physician verification, and the expansion of the reasonable alternative requirement. In the small group market, there also is uncertainty about how the wellness rule is intended to interact with the new rating rule for tobacco use. Employers, insurers, and service providers that offer or work with wellness programs should consider whether to comment on the proposed rule and should watch for a final rule and any future guidance in 2013, in order to be ready for compliance in 2014.

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