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TO: **Clients and Colleagues**
FROM: **Christine P. Roberts**
RE: **How Genetic Privacy Regulations Impact Wellness Programs**
DATE: **November 10, 2009**

FAQs re: Legal Standards Governing Wellness Programs

Q.1: What is a wellness program?

A.1: A wellness program may take many forms but its most common feature usually is a financial reward to encourage healthier lifestyles. Common examples include reduced premiums or co-pays in exchange for quitting smoking or reducing weight or cholesterol levels.

Q.2: What laws govern wellness programs?

A.2: Several federal laws govern wellness programs, including the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Genetic Information Nondiscrimination Act of 2008 ("GINA"), and the Americans with Disabilities Act of 1990 ("ADA")

Q.3: What does HIPAA require of (or disallow in) wellness programs?

A.3: HIPAA generally prohibits discrimination, in the provision of health benefits, on the basis of health conditions, claims experience, genetic information, and other health factors. With specific respect to wellness programs, HIPAA distinguishes between participation-only programs that do not reward participants based on a health factor, and standard-based programs that provide rewards based on a health factor. HIPAA does not impose requirements on participation-only wellness programs, such as reimbursement of health club memberships, and reimbursements for smoking cessation programs, regardless of outcome. HIPAA does impose 5 separate requirements on the standard-based wellness programs that reward participants for meeting standards related to health factors:

1. The reward must be equal to no more than 20% of the cost of coverage.
2. The wellness program must be reasonably designed to promote health or prevent disease.
3. The program must give individuals an opportunity to qualify for the reward at least once a year.
4. The reward must be available to all similarly situated individuals. Objective distinctions based on bona fide business classifications, such as employees versus retirees, employees versus spouses/dependents, etc. are permissible.

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5. The wellness program must disclose that alternative standards (or waivers) are available, to account for individuals with disabilities or other conditions that make successful completion of the wellness program difficult or impossible.

Q.4: What is GINA and what does it require of (or disallow in) wellness programs?

A.4: GINA is the Genetic Information Nondiscrimination Act of 2008. GINA amends HIPAA and other laws with regard to genetic information, which means information about (a) an individual's genetic tests; (b) the genetic tests of the individual's family members; and (c) the manifestation of a disease or disorder in a family member (e.g., family medical history). Genetic information might also include an individual's request for or receipt of genetic services. It does not include information about an individual's sex or age.

Interim final regulations under GINA were published on October 7, 2009 by the Department of Labor, the Department of Health and Human Services, and the Treasury Department. The regulations are effective January 1, 2010 for calendar year plans. The regulations most directly affect wellness programs in two ways:

1. They prohibit health plans from requesting genetic information "prior to or in connection with enrollment" in the plan.
2. They prohibit health plans for collecting genetic information at any time "for underwriting purposes." Under the regulations, the payment of virtually any type of financial incentive will be classified as "for underwriting purposes," including any discount or rebate in premiums/contributions and any discount, rebate, or other change in a deductible, co-payment or co-insurance.

Financial incentives are often tied to completion of health risk assessments ("HRAs") which in turn often ask about family medical history. This practice is now disallowed under the GINA regulations. The following FAQs relate specifically to HRAs as they are common wellness program elements.

Q.5: What are some examples of HRAs that do not meet new GINA standards?

A.5: As mentioned above, a wellness program that provides rewards (e.g., discounts on premiums/deductibles) in exchange for completing an HRA that requests genetic information, including family medical history, violates GINA's prohibition against collecting genetic information for underwriting purposes. There are no exceptions to this rule. Also, GINA prohibits requesting completion of an HRA that requests genetic information (e.g., family medical history) prior to enrollment in a health plan. A program that conditions eligibility for additional benefits such

as enrollment in a disease management program on completion of an HRA that requests genetic information also violates GINA. Finally, "broadly worded" HRAs that ask "is there anything else relevant to your health that you would like us to know or discuss with you?" violate GINA unless the same HRAs expressly warn participants not to provide genetic information such as family medical history, genetic testing results, etc.

Q.6: What are some examples of HRAs that meet the new GINA standards?

A.6: An HRA that is stripped of any genetic information questions, including reference to family medical history, meets GINA standards whether provided before enrollment or otherwise. Alternatively, an HRA that requests genetic information but provides no rewards or financial incentives, and that is not to be completed until after enrollment, is permissible. A third strategy is to use to HRAs in tandem. The first HRA does not request genetic information but offers a reward for completion. The second HRA offers no reward for completion but request genetic information. This second HRA must expressly state that its completion is totally voluntary and will not affect any rewards offered for completing the first HRA. Finally, providing financial incentives for HRA completion outside of the group health plan – such as in the form of taxable compensation – is permitted under GINA.

Q.7: What does the ADA require of (or disallow in) wellness programs.

A.7: The Equal Employment Opportunity Commission has earlier issued informal opinion letters stating that disability-related questions are permissible only as part of a "voluntary wellness program" – where participants are not required to participate or penalized for failing to do so. The EEOC issued two additional informal opinion letters in 2009 on this topic. In its March 6, 2009 opinion letter the EEOC found that an employer who conditioned participation in a self-funded group health plan on completion of a health risk assessment violated the ADA. In its August 10, 2009 letter the EEOC explained that an employer may only ask disability-related questions of employees if the questions are "job related and consistent with business necessity." The EEOC went on to state that asking questions about various medical conditions that are typical of many HRAs – such as questions on heart disease, cancer, asthma, etc. – before granting reimbursement of health expenses was not job related or consistent with business necessity. These informal opinion letters are not binding but do provide some insight into how the EEOC is viewing the type of inquiries made in the HRA and wellness program context.