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CLIENT E-NEWSLETTER

BENEFITS UPDATE

Wellness Program Affected by Genetic Information Nondiscrimination Regulations And HIPAA Privacy Proposed Regulations

On October 7, 2009, the Departments of Treasury (Treasury), Labor (DOL) and Health and Human Services (HHS) issued interim final regulations concerning nondiscrimination rules of the Genetic Information Nondiscrimination Act (GINA). These rules may change how some wellness programs operate if they request health risk assessments.

As background, GINA amended the Health Insurance Portability and Accountability Act (HIPAA) portability rules, added rules concerning genetic information with respect to group health plans and insurance issuers (requiring changes to the HIPAA privacy regulations discussed below), and prohibited employment discrimination based on genetic information. The three agencies issued interim final regulations to interpret the rules prohibiting discrimination by group health plans and health insurance issuers based on genetic information. Importantly, the term "genetic information" is defined to include family medical history.

These rules apply to group health plans for plan years beginning on or after December 7, 2009. Thus, the effective date for calendar-year plans is January 1, 2010. The following is a summary of the rules affecting group health plans:

Underwriting. The regulations broadly prohibit collecting genetic information for underwriting purposes. A plan may not collect genetic information (including family medical history) either for purposes of eligibility for benefits or for computing premiums or contributions. A wellness program may not give a reward (including discounts, rebates, payments in kind, or other premium differential mechanisms) in return for completing a health risk assessment that has questions about family medical history. A health risk assessment may not ask questions about family medical history if completing the assessment may qualify an individual to participate in a disease-management program. The regulations reason

that both the reward and eligibility for the disease-management program are considered underwriting.

Prior to or in Connection With Enrollment. A group health plan may not collect genetic information before or in connection with enrollment, even if the information is not to be used for underwriting. There is an exception if genetic information is collected incidental to the collection of other information as long as the collection is not for underwriting. Thus, a health risk assessment requested before enrollment may not include questions about family medical history, even if there is no associated reward or penalty.

The regulations include several other important rules related to *genetic* information:

Discrimination Based on Genetic Information. A group health plan may not adjust premiums or contributions for the plan, or for any group of similarly situated individuals under the plan, on the basis of genetic information (including

family medical history). Premiums for a group can be based on diseases that have manifested themselves in covered persons but may not be based on genetic information (including family medical history).

Medical Appropriateness. Plans may use genetic information to determine if a benefit is medically appropriate without violating the prohibition on using genetic information for underwriting. However, they may use only the minimum information necessary.

Genetic Tests. A group health plan may not request or require an individual or a family member of the individual to undergo a genetic test. However, a health care provider (including an HMO physician) may order a genetic test as part of the individual's treatment. The plan can require a covered person to provide a genetic test if it is necessary to determine whether a benefit is payable under the plan. For example, the medical necessity of a treatment may be demonstrated by a genetic test. However, the plan may not request more than the minimum information necessary to make the determination.

Changes for Wellness Programs. Based on the interim final nondiscrimination regulations, beginning January 1, 2010 (for calendar year plans), health risk assessments that include family medical history questions will be prohibited before and in connection with enrollment. After enrollment, health risk assessments that include family medical history questions will be permitted only if they have no associated

reward or penalty and if they do not qualify the individual to participate in a disease-management program.

HIPAA Privacy Proposed Regulations. On the same day, the HHS proposed changes to the HIPAA privacy regulations in light of GINA. The proposed regulations would prohibit health plans from using or disclosing protected health information (PHI) that is genetic information for underwriting purposes, even if an individual has signed an authorization. They would add several definitions to conform with those in the nondiscrimination regulations described above and would modify the definition of "health information" so the term includes genetic information. The proposed regulations would provide that if a health plan intends to use or disclose PHI for underwriting purposes, the notice of privacy practices must include a statement that the plan is prohibited from using or disclosing *genetic* information for underwriting purposes. The preamble requests comments on ways to inform individuals of this change to the notice of privacy practices without unduly burdening health plans. The proposed changes to the regulations would be effective for all health plans 180 days after they are finalized.

EEOC Letter: Requiring Health Risk Assessment to Participate in Medical Plan Violates the ADA

In a recent "informal discussion letter" (which does not constitute the Commission's formal opinion), the Equal Employment Opportunity Commission (EEOC) concluded an employer would violate the Americans with Disabilities Act (ADA) if it required an employee to complete a health risk assessment that includes disability-related questions as a condition of participating in a medical plan.

As a reward for completing a health risk assessment, the employer wanted to offer employ-

ees participation in a health reimbursement account (HRA). These accounts are entirely employer-funded and generally reimburse expenses that are not covered under the major medical plan. The health risk assessment asks employees to answer more than 100 questions in several categories, including family health history, self care, personal health, women's health, older adult health, health choices-nutrition, health choices-physical activity, health choices-alcohol and tobacco, health choices-safety, and health changes.

The EEOC stated the ADA strictly limits when an employer may obtain medical information from applicants and employees. Before a job offer is made, the ADA prohibits all disability-related inquiries and medical examinations, even if they are job-related. After a conditional offer is made, an employer may ask disability-related questions and require medical examinations as long as the employer does so for all new employees in the same job category. Once employment begins, an employer generally may make disability-related inquiries and

require medical examinations only if they are job-related and consistent with business necessity. This standard may be met when an employer "has a reasonable belief, based on objective evidence, that: (1) an employee's ability to perform essential job functions will be impaired by a medical condition; or (2) an employee will pose a direct threat because of a medical condition." Disability-related inquiries and medical examinations are also permitted if they follow up on a request for reasonable accommodation or if the examination or other monitoring is conducted under specific circumstances (e.g., periodic medical examinations required of employees in positions affecting public safety). Finally, disability-related inquiries and medical examinations are permitted as part of a voluntary wellness program. A wellness program is voluntary if employees are neither required to participate nor penalized for nonparticipation.

The letter said that requiring employees to complete a health risk assessment that includes many disability-related inquiries as a prerequisite to obtaining reimbursement for health expenses does not appear to be job-related and consistent with business necessity. As examples, it cited questions as to how often they feel depressed; whether they have ever been told they have certain conditions, such as asthma, cancer, heart disease, or diabetes; how many different prescription medications they currently take; or how much alcohol they drink. Since all employees are required to complete a health risk assessment as a prerequisite for eligibility for a health insurance program, there is no indication the employer has concerns that a particular employee will be unable to do his job or will pose a direct threat because of a medical condition. The employer did

not appear to the EEOC to be obtaining medical information in response to a request for reasonable accommodation or because it is monitoring employees in positions affecting public safety.

Finally, even if the health risk assessment could be considered part of a wellness program, it is not voluntary because it penalizes any employee who does not complete the questionnaire by making him or her ineligible to receive reimbursement for health expenses. The letter thus concluded that the ADA prohibits requiring employees to complete the health risk assessment in order to be covered under the HRA. The letter also included a footnote saying that as of November 21, 2009, the employer's health risk assessment would likely violate GINA if it asks about an employee's family medical history (these rules are discussed in the prior article).

Regulations on Notification of Breaches of Unsecured Protected Health Information

The HHS and Federal Trade Commission (FTC) recently promulgated regulations concerning the new breach notification requirements that were part of last February's stimulus law, the American Recovery and Reinvestment Act of 2009 (ARRA). The requirements relate to breaches of unsecured PHI in violation of HIPAA privacy and security requirements. The HHS notification requirements apply to covered entities (such as group health plans) and business associates. FTC rules require certain entities that are not covered by HIPAA to notify consumers when the security of their individually-identifiable health information is breached. The regulations also revise prior rules on technologies or methodologies that render PHI unusable, unreadable, or indecipherable to unauthorized individuals.

The following are highlights of the HHS rules as they relate to group health plans:

Effective Dates. The HHS interim final regulations are effective September 23, 2009, but penalties will not be imposed for notification failures with respect to breaches discovered before February 21, 2010. The FTC final regulations are effective September 24, 2009, and full compliance will be required by February 22, 2010.

Unsecured Definition. The notification rules apply to unsecured PHI. PHI is "unsecured" if it is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of technologies and methodologies the HHS specifies on its web-

site. Currently only encryption and destruction are approved technologies. Redaction is specifically excluded as a means of data destruction.

Breach Definition. The HHS interim final regulations define a "breach" that will trigger the notice requirement as the acquisition, access, use, or disclosure of PHI in a manner not permitted under the privacy rules that compromises the security or privacy of the PHI. The security or privacy of PHI is compromised if there is "a significant risk of financial, reputational, or other harm to the individual." The preamble to the regulations states this requires a fact-specific risk assessment that considers who used or received the impermissible disclosure. For example, if the disclosure is to another HIPAA-covered entity that has HIPAA privacy and security obligations, the risk may not be significant, so no reporting would be required. The risk also may not be significant if the plan takes steps to mitigate the breach, such as by obtaining satisfactory assurances the PHI will not be further used or disclosed.

Breach Notification. Following the discovery of a breach of unsecured PHI, the regulations require a group health plan to notify each individual whose unsecured PHI has been, or is reasonably believed by the plan to have been, accessed, acquired, used, or disclosed as a result of such breach. Notice must also be given to HHS. Following discovery of a breach of unsecured PHI involving more than 500 residents of a state or jurisdiction, a plan must notify prominent media outlets serving the state or jurisdiction as well as HHS. Business associates must notify the plan.

Unless law enforcement officials request a delay, notice must be made without unreasonable delay and in no case later than 60 calendar days after discovery

of a breach. The notice must include, to the extent possible:

- *A brief description of what happened, including the date of the breach and the date it was discovered, if known;*
- *A description of the types of unsecured PHI involved in the breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information);*
- *Any steps individuals should take to protect themselves from potential harm resulting from the breach;*
- *A brief description of what the plan is doing to investigate the breach, to mitigate harm to individuals, and to protect against any further breaches; and*
- *Contact procedures for individuals to ask questions or learn additional information, including a toll-free telephone number, e-mail address, Website, or postal address.*

The regulations give details of how to send the notice, procedures for deceased individuals, substitute notices if there is insufficient information or out-of-date contact information, and additional telephone notice in urgent situations.

Finally, the regulations make coordinating changes to HIPAA's existing requirements in light of the breach notification rules. These include the workforce training rules, complaint procedures, sanction rules, policies and procedures, and anti-coercion provisions.

Shorter Plan-Imposed Statute of Limitations Was Properly Disclosed

The Employee Retirement Income Security Act (ERISA) does not contain a statute of limitations (i.e., deadline for bringing a lawsuit) for claims by an employee to recover benefits. Most courts use the most analogous state law limitations period, which is usually the state's contract limitations period. For example, in Louisiana, the federal courts have ruled

that employees have 10 years within which to bring a lawsuit to recover benefits. Some employers have amended their plans to specify shorter limitations periods.

In a recent U.S. Ninth Circuit Court of Appeals case, the short-term and long-term disability plan pro-

vided that the limitations period was one year after the claim was denied on appeal. A former employee sued her employer's self-funded short-term disability plan after the disability administrator denied her claim for benefits. The trial court dismissed her lawsuit because it was filed 20 days after the end of the plan's limitations period.

On appeal, the employee made two arguments why the plan's one-year limitations period should not apply to her. First, she argued the limitations period did not satisfy the "doctrine of reasonable expectations" because it was not explained in the appropriate section of the summary plan description and should have been displayed more prominently. It was explained on the last page of the disability chapter of the summary plan description, under a bold heading "Claims Appeal Procedure." The employee contended it should have been put in the administrative chapter of the summary plan description, rather than the disability chapter. Second, she argued the limitations period should have been included in the letter denying her claim on appeal. Instead, the letter advised the employee to consult the summary plan description for information regarding her rights.

The court of appeals agreed with the trial court's dismissal of the case as filed too late. The court rejected the employee's reasonable expectations argu-

ment without deciding whether that doctrine, which generally applies only to insurance contracts, applies to self-funded plans. Even if the doctrine applied, the court ruled that the summary plan description met plan participants' reasonable expectations in addition to fulfilling the statutory and regulatory requirements. It was written in a manner calculated to be understood by the average plan participant. It was sufficiently accurate and comprehensive to reasonably apprise participants of their rights and obligations under the plan. The deadline was not minimized or otherwise obscured. Since the limitations provision was placed in the disability section, it was placed near the benefits provisions. The letter from the carrier referred her to the summary plan description and a reasonable participant seeking disability benefits would have read the disability section and found the limitations period.

Finally, the appeals court also rejected the employee's argument that the court should adopt a state law insurance rule that if the limitations period was not mentioned in the correspondence from the carrier, it should be waived. The court was reluctant to extend ERISA's requirements beyond those Congress chose to impose. Doing so would lead to inconsistent rules in different parts of the country. It also observed that two other federal circuits have declined to adopt such a requirement.



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