



## **The “Risk” in Health Risk Assessments: Calendar Year Plans Beware**

**October 26, 2009**

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On October 7, 2009 the Departments of Labor (DOL), Treasury (IRS), and Health and Human Services (HHS) issued an Interim Final Rule for implementing the provisions of the Genetic Information Non-discrimination Act of 2008 (GINA).

This Interim Final Rule takes effect on December 7, 2009 (60 days from publication) applying to plan years beginning on or after that date. These rules directly affect calendar year plans.

**GINA in Employment Practices.** The Interim Final Rule also discusses the handling of Genetic Information in the context of employment. Our Memorandum covers only the rules applicable to group health plans.

### **The Risk: Immediate Non-compliance**

In recent years, Plan Sponsors have used Health Risk Assessments in combination with bonafide wellness programs pursuant to the Health Insurance Portability and Accountability (HIPAA) regulations and disease management programs as a method to encourage healthy lifestyles and to promote health awareness. Calendar year Plan Sponsors may be at immediate risk of non-compliance with these new rules if they seek, use, or reward the collection of Genetic Information, while conducting open enrollment for the plan year beginning January 1, 2010!

### **Non-compliance**

Here are some of the key areas of risk to all plan sponsors under the new rule regardless of the plan year:

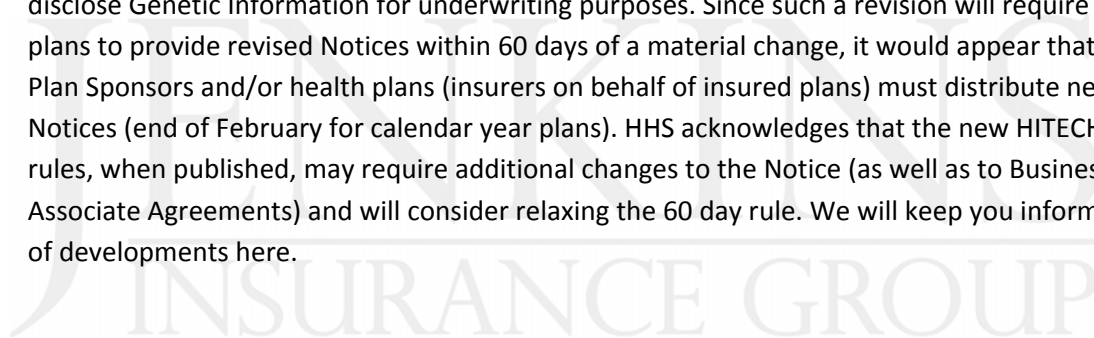
1. Using a Health Risk Assessment that seeks Genetic Information (e.g. family history of cancer, diabetes, etc.) in conjunction with a plan’s annual open enrollment or any item before the employee’s effective date of coverage;

2. Providing incentives/rewards (e.g. \$100; premium contribution reduction) for completion of a Health Risk Assessment containing a request for Genetic Information;
3. Using the Genetic Information as a screening device to determine participation in a disease management program, wellness initiative, or the receipt of medical plan benefits (e.g. “based on your answers to these questions, we will enroll you in our enhanced benefits program/disease management program.”); and,
4. Using Genetic Information for underwriting purposes.

### Details

1. **GINA Generally.** The Genetic Information Non-discrimination Act of 2008 (GINA) prohibits employers, health plan sponsors, and health insurers from discriminating on the basis of an individual’s Genetic Information in group health plans (Title I) and in employment practices (Title II).
2. **Genetic Information.** Genetic Information means information about an individual’s genetic tests, the genetic tests of that individual’s family members, and the manifestation of a disease or disorder in family members of the individual. Family members mean siblings, parents, other relatives by blood, marriage, or adoption. Genetic Information also includes any request for, or receipt of, genetic services or participation in clinical research that includes genetic services. However, Genetic Information does not include the individual’s gender or age.
3. **Genetic Tests.** Genetic Test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.
4. **Genetic Services.** Genetic Services includes genetic counseling or genetic education.
5. **Manifestation.** The manifestation of a disease or disorder is NOT “Genetic Information” and is not subject to the new GINA rules. It is important to note that manifestation means a condition which has been diagnosed, or would have been diagnosed by a health care professional based on symptoms other than Genetic Information. As a result, an HRA can ask whether the enrollee/employee has had a particular disease or disorder, without violating the Interim Final Rule.
6. **Genetic Questionnaires.** A Plan Sponsor may ask for the completion of a Genetic Questionnaire as long as:
  - a. It is after the effective date of coverage;
  - b. It is voluntary; and,
  - c. has no effect on benefits, premium contributions, or other rewards.
7. **Rewards.** A Plan Sponsor may also offer an incentive or reward for completion of an Health Risk Assessment which does not request Genetic Information.

8. **Proper Use of Genetic Information.** A group health plan may use available Genetic Information or genetic test results to determine payment for treatment and services, but may only use the minimum information necessary to the task. We must point out that GINA requires that Genetic Information be treated as Protected Health Information under the Health Insurance Portability and Accountability Act Privacy Rules. For purposes of GINA, Genetic Information includes information regarding dental and vision in addition to medical information.
9. **Using Genetic Information in a Disease Management Program.** If the disease management program participation is voluntary, and the eligible employee formally applies for participation in the program, the information can be used to determine eligibility. If the program is mandatory, it must be based on the manifestation of the disease and not on any Genetic Information.
10. **Prohibition.** Genetic Information cannot be used for underwriting purposes. Under the Interim Final Rule, underwriting is defined to include:
  - a. Premium rate adjustments based on genetic tests;
  - b. Premium reductions based on Genetic Information;
  - c. Application of a pre-existing condition limitation; and,
  - d. The marketing or obtaining of health insurance policies and related activities.
11. **Penalties.** Violations of the new GINA rules can result in penalties starting at \$100 per day per each individual to whom a failure occurs up to a maximum of \$500,000.
12. **EEOC's Views on HRAs.** On March 6, 2009, the Equal Employment Opportunity Commission (EEOC) released an informal Opinion Letter prohibiting the practice of requiring completion of a Health Risk Assessment (with or without Genetic Information requests but containing disability related inquiries) as a condition for participation in a company-sponsored health plan. Although the EEOC relies on the Americans with Disabilities Act and various HIPAA "Bonafide Wellness Program" rules, its opinion is also consistent with the underwriting prohibitions contained in the GINA Interim Final Rule.
13. **HIPAA Notice of Privacy Practices.** The Interim Rule will require a Plan's Notice of Privacy Practices (Notice) to include a specific provision stating that health plans may not use or disclose Genetic Information for underwriting purposes. Since such a revision will require plans to provide revised Notices within 60 days of a material change, it would appear that Plan Sponsors and/or health plans (insurers on behalf of insured plans) must distribute new Notices (end of February for calendar year plans). HHS acknowledges that the new HITECH rules, when published, may require additional changes to the Notice (as well as to Business Associate Agreements) and will consider relaxing the 60 day rule. We will keep you informed of developments here.



## Action Plan

1. **Health Risk Assessments.** Review your use of Health Risk Assessments (HRAs) if any. If it contains questions eliciting Genetic Information, remove these questions. If it is a condition for participation in the plan, remove that requirement and add a sentence providing clear instructions not to provide Genetic Information. If there is a reward, such as a premium reduction or other health benefit used to encourage completion of the HRA, then remove the reward. If the HRA also is tied to a disease management program (see Paragraph 3 under Non-compliance) then uncouple the link.

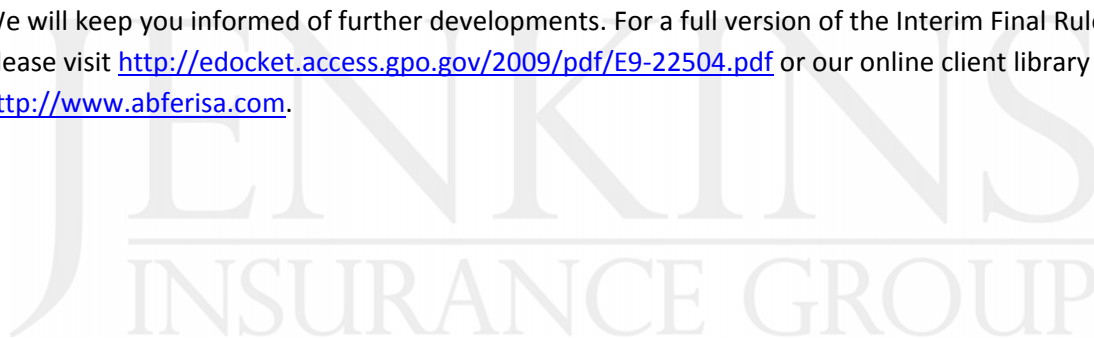
If you already have implemented the HRA in conjunction with a 2010 enrollment, then contact your benefits advisor on corrective action. Options include:

- a. Removing the Genetic Information questions, destroying the completed HRAs, and offering them for completion again;
  - b. Turning the incentive into a bonus for all plan participants (e.g. cash, lowered premium contributions, etc.) regardless of whether they have completed the HRA;
  - c. Modifying rules for participation in disease management. Allow individuals to participate voluntarily;
  - d. Collecting Genetic Information on a voluntary basis after the plan year has begun without offering an inducement;
  - e. Exercising other options based on specific non-compliant elements.
2. **HIPAA Compliance.** Review the plan's Notice of Privacy Practices and Business Associate Agreements for compliance with the GINA Interim Final Rule. You also may want to add language to the plan document and SPD specifically prohibiting the use of Genetic Information for underwriting purposes.

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The GINA Interim Final Rule was issued through the combined efforts of the DOL, the IRS, and HHS. Each has jurisdiction over the implementation of the Rule. All of these agencies appear to be prepared to enforce the Rule as of the first plan year beginning on or after December 1, 2009. I recommend that plan sponsors review the current practices, especially with regard to Health Risk Assessments used in the open enrollment process and ties to bonafide wellness programs and disease management programs.

We will keep you informed of further developments. For a full version of the Interim Final Rule please visit <http://edocket.access.gpo.gov/2009/pdf/E9-22504.pdf> or our online client library at <http://www.abferisa.com>.



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