

# Legislative Brief

## The Genetic Information Nondiscrimination Act of 2008: Interim Final Regulations Issued



The Genetic Information Nondiscrimination Act of 2008 (“GINA”) was enacted on May 21, 2008. GINA provides broad protections in employment and health benefits against the improper collection, use or disclosure of employees’ genetic information, in part by amending a number of major laws such as ERISA, HIPAA and the IRC. The employment provisions of GINA become effective 18 months after the date of enactment (i.e., **November 21, 2009**), while the provisions targeted at insurers go into effect for plan years beginning one year after the date of enactment (i.e., **May 21, 2009**, but the effective date for calendar year plans is **January 1, 2010**).

Interim final regulations (the “Regulations”), which provide guidance on how GINA affects wellness and disease management programs, were issued on October 7, 2009. The Regulations apply to plan years beginning on or after **December 7, 2009**, which is also **January 1, 2010** for calendar year plans.

This issue of the Benefit Development Group Legislative Brief provides a brief overview of the aspects of GINA affecting health plans and the Regulations.

### Important Definitions

The Regulations clarify definitions of some key terms related to GINA. Some important terms are:

Genetic Information - means information about:

- an individual’s genetic tests,
- the genetic tests of family members of the individual, and
- the manifestation of a disease or disorder in family members of the individual.

Genetic information also includes any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by the individual or any family member of the individual. The genetic information of any fetus carried by a pregnant woman and the genetic information of any embryo legally held by an individual or family member using assisted reproductive technology are also considered genetic information protected by GINA. The term does not include information about the sex or age of any individual.

Family Member – means a dependent or any other person who is a first-, second-, third- or fourth-degree of the individual or of the individual’s dependent. Relatives by marriage or adoption are treated the same as biological relatives. Also, relatives such as half-siblings are treated as full siblings.

Genetic Services – means a genetic test, genetic counseling or genetic education.

### Overview of GINA

GINA contains requirements related to genetic nondiscrimination in health insurance. These requirements regulate group health plans (including small group health plans), health insurance issuers offering health insurance coverage in the individual market, non-federal governmental plans and issuers of Medicare supplemental policies.

In general, GINA prohibits group health plans and insurance issuers from:

- adjusting group premium or contribution amounts on the basis of genetic information;
- requesting or requiring individuals (or their family members) to undergo a genetic test (with limited exceptions such as for determinations regarding payment based on medical appropriateness); and
- collecting genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

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### Impact on Use of Health Risk Assessments (Title I of GINA and the Regulations)

The Regulations clarify that GINA's prohibition on collecting genetic information prior to or in connection with enrollment, or for underwriting purposes, will affect the use of Health Risk Assessments ("HRAs"). HRAs are tools commonly used by wellness and disease management programs.

Pursuant to the Regulations, group health plans may not:

- provide a reward or incentive to an individual for completing an HRA that requests genetic information, such as family medical history; or
- request genetic information as part of an HRA that must be completed before enrollment in the plan or eligibility for additional benefits under the plan, such as a disease management program.

A reward or incentive can take many forms, including premium discounts or rebates, reduced deductibles or copayments, cash rebates or gift certificates. The regulations suggest that rewards or incentives also include those related to health flexible spending arrangement or health reimbursement arrangements. Rewards or incentives do not have to be based on the outcome of the HRA to be impermissible.

The Regulations indicate however, that the following uses or types of HRAs will **not** violate GINA:

- Collecting genetic information after enrollment in the plan if no reward or incentive is provided;
- Using two separate HRAs – one that requests genetic information and one that does not. The HRA requesting genetic information must not include an incentive, must be voluntary and must not affect the reward given for the other HRA; or
- Asking HRA questions that do not directly request genetic information, if the HRA clearly states that genetic information should not be provided.

### Actions to Take Now

Plan sponsors should become familiar with the interim final regulations and review their health plans to be sure they do not inappropriately request or receive genetic information, and evaluate whether any changes are necessary regarding the administration of benefits. Specifically, plan sponsors must review their wellness and disease management programs to ensure that they do not impermissibly collect genetic information, through the use of HRAs or otherwise.

For a copy of GINA, see: [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_bills&docid=f:h493enr.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h493enr.txt.pdf)

For a copy of the Regulations, see: <http://edocket.access.gpo.gov/2009/pdf/E9-22504.pdf>

If you have questions regarding this important and emerging area, please contact your [b\_officialname] representative.

This Benefit Development Group Legislative Brief is not intended to be exhaustive nor should any discussion or opinions be construed as legal advice. Readers should contact legal counsel for legal advice.