

Update

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Genetic nondiscrimination rules affect health plan practices

New [regulations](#) explain how the Genetic Information Nondiscrimination Act (GINA) restricts insured and self-insured group health plans' ability to collect or use family medical history and other genetic information. The rules will affect the scope and timing of health assessments (HAs), wellness incentives and other health plan practices involving genetic information. Employers may need to revise health plans to comply with the regulations, which take effect for plan years starting on or after Dec. 7, 2009 (Jan. 1, 2010, for calendar-year plans). For background on GINA's broader scope and general requirements, see Mercer's earlier [Update](#) (June 11, 2008).

Scope of GINA regulations

Title I of GINA ([Pub. L. No. 110-233](#)) restricts how group health plans and health insurers collect – such as by requesting or requiring – and use genetic information. Genetic information includes the following (see page 2 sidebar for more definitions):

- Genetic tests, counseling or education requested or received by an individual or family member
- Family medical history – that is, any disease or disorder manifested by an individual's family members

While family medical history is protected genetic information, an individual's own medical history is not. Once someone has developed symptoms of a disease or disorder, related medical records – other than genetic tests – are not subject to GINA.

Group health plan restrictions

Under GINA, group health plans and insurers cannot:

- Collect any genetic information before or in connection with enrollment (see page 3 sidebar)

GINA definitions

Family members. The definition of family members extends to spouses; dependents, including foster or adopted children; and relatives to the fourth degree (for example, a great-great grandparent). GINA's protections also apply to genetic information about an individual's fetus or an embryo.

Genetic tests. These tests involve analysis of human DNA, RNA, chromosomes, proteins or metabolites that detect genotypes, mutations or chromosomal changes. Results of tests used to screen for disease before an individual manifests any symptoms are protected genetic information, but lab work done to diagnose the cause of symptoms already manifested is not protected.

Manifested. A "manifested" disease, disorder or condition is one that has been or reasonably could be diagnosed.

- Collect genetic information at any time for any of these underwriting purposes:
 - Determining plan eligibility (for initial or continued enrollment) or coverage, including basing deductibles or other cost-sharing mechanisms on activities such as completing an HA or participating in a wellness program
 - Computing group premiums or employee contributions, including offering discounts, rebates, payments in kind or other premium differentials
 - Imposing pre-existing condition exclusions
 - Establishing, renewing or replacing health benefits or insurance contracts
- Require or request an individual or family member to undergo genetic testing at any time – before, during or after enrollment

Exceptions. Despite the broad ban on collecting genetic information before enrollment, using that information for underwriting purposes or requesting genetic tests at any time, GINA has some exceptions for group health plans:

- **Claims substantiation.** Group health plans can request genetic test results, if needed, for claims substantiation or other payment purposes. For example, if an asymptomatic woman who tests positive for the BRCA gene for early onset breast cancer undergoes a prophylactic mastectomy, the plan processing her claim may request her genetic test results to substantiate her need for surgery.
- **Medical appropriateness.** Plans can request genetic information to determine whether a service or treatment is medically appropriate. For example, if a 30-year-old woman whose mother and sister had early onset breast cancer follows her doctor's advice to begin getting annual mammograms, a plan that only covers mammograms starting at age 40 unless a medical need exists can request her family medical history to determine if this screening is merited.
- **Incidental collection.** No GINA violation occurs if a plan "incidentally" collects genetic information while asking for or receiving other information before enrollment. However, this exception will not apply if the plan reasonably could have anticipated that its request would elicit genetic information but didn't specifically instruct individuals not to provide genetic information.

Impact on common group health plan practices

Group health plans that currently gather HAs from participants or prospective enrollees will need to assess whether the timing and type of information collected comply with GINA's restrictions.

Pre-enrollment questions. The table below illustrates how GINA affects health questionnaires distributed before or as part of enrollment.

Does GINA permit asking employees questions on these topics before enrollment?		
Topic	About self	About family member
Age, gender and other demographic factors	Yes	Yes
Prescription drug use, diagnosed diseases or medical conditions	Yes	No
Prior surgeries and other past medical history	Yes	No
Eating habits and physical activity levels	Yes	Yes
Genetic test results	No	No

Incentives for completing HAs. Employers should take a careful look at any plan incentives offered – such as discounted premiums – in exchange for participating in HAs, disease management programs or wellness activities. If questions on the HA ask about family medical history or other genetic information, any related plan incentives could run afoul of GINA's underwriting restrictions. Nor can plans ask genetic-related questions to determine whether an individual qualifies for a disease management or wellness program.

Timing and type of HA	Does GINA permit HA?	
	With family medical history questions	Without family medical history questions
Pre-enrollment HA	No	Yes
Post-enrollment HA with plan incentive	No	Yes
Post-enrollment HA with no plan incentive	Yes	Yes

Note: Even if GINA's group health plan rules don't apply, other laws may have relevant restrictions.

Next steps

GINA could have a significant effect on current plan practices related to family medical histories and other genetic information. Employers should take these steps to review their plan designs for compliance:

- Identify plan practices that include requests for family medical history or other genetic information, such as HAs, and disease management programs or wellness activities.

2009 open-enrollment Q&A

Question: Do GINA's restrictions on pre-enrollment activities – such as requests for family medical history – apply to the current open-enrollment season for calendar-year plans, even though the compliance date for these plans isn't until Jan. 1, 2010?

Answer: This issue is not entirely clear. Informal comments by government officials indicate that compliance isn't required until the effective date, so collecting genetic information in the fall of 2009 may be permissible, as long as it isn't used in a prohibited way after Jan. 1, 2010 (for example, to adjust 2010 plan premiums or contributions). However, employers should consult legal counsel when deciding how to handle this year's open-enrollment materials and communications.



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- Revise those practices as needed to comply with GINA, including these steps:
 - Remove all genetic information requested before or during enrollment.
 - Collect genetic information after enrollment, but do not use it for underwriting or other prohibited purposes.
 - Offer plan incentives only for completing HAs that don't ask for genetic information.
- Discuss GINA compliance with all relevant third-party administrators and vendors, and modify vendor contracts, if needed, to include compliance obligations.
- Consider whether GINA's protections will encourage more participants to pursue genetic testing or related services and how that could affect a group health plan's costs or coverage.
- Determine whether genetic information is currently used to set group premiums or contributions; if so, discontinue that practice.

GINA is just one of many laws that affect HAs and disease management programs. Plan sponsors that comply with GINA must keep in mind how other legal restrictions, such as GINA's employment practices provisions, HIPAA's nondiscrimination rules ([Update](#), March 12, 2008) and the Americans with Disabilities Act come into play.

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