

Title I of GINA

- Definitions
- Impact on Practices
- Research Exception
- Request or Require a Genetic Test
- Payment
- Enforcement

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- Definitions
 - Genetic information
 - Genetic test
 - Manifest disease
 - Genetic services
 - Underwriting

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- Definitions
 - Genetic information
 - *Protected no matter when discovered or obtained.

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- Definitions

- Genetic information
- Genetic test
 - “Analysis of human DNA, RNA, chromosomes, proteins, or metabolites, to detect genotypes, mutations, or chromosomal changes.”
 - Regulators should include non-exclusive list of examples based in Congressional intent. (*some techniques like RNA expression arrays and methylation, should be included but may require consultation with scientific experts).
 - “Exceptions” (i) and (ii) don’t add much meaning beyond emphasizing that if related to manifest disease, probably not protected and a genetic test result by itself is not a disease.

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- Definitions

- Genetic information
- Genetic test
- Manifest disease
 - A genetic test result is not a disease.
 - But family history of disease is genetic information.
 - Regulators should pay attention to how information about manifest disease is used.

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- Genetic information
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- Genetic services
 - Genetic services explicitly includes testing, counseling, and education.
 - *Regulations should define genetic services to include information about preventive therapies and screenings stemming from a genetic test, which a patient may *consider or undergo*. Good public policy and the point of GINA.

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- Definitions

- Genetic information
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- Underwriting
 - Must be consistent with HIPAA. Genetic information is health information that could legally be used in underwriting under HIPAA but not under GINA.

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- Definitions
- Impact on Practices
 - Collection
 - Incidental collection
 - Individual market
 - Group market
 - Wellness programs

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- Definitions
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 - May not ask about family history.

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 - Incidental collection
 - Additional guidance is needed. Insurers should include regulator-required model language to avoid it.
 - Certify, isolate, protect, and destroy.

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 - Individual market
 - In current practice, insurers do see this information, often through requests for complete medical records.

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 - Group market
 - In group market, insurers see this information, often through experience rating and claims reviews.

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- Definitions
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 - Group market
 - Wellness programs
 - If it smells like an insurance company, no collecting GI, no family history questions.

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- Impact on Practices
- Research Exception
 - This exception to the “no requests” rule, and its five protections, should include any research *conducted or funded* by a health insurance company.
 - Written voluntary informed consent is key. No opt-outs or “not practicable” exceptions under IRBs.
 - Information must be isolated from underwriting.

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- Request or Require a Genetic Test

- “Requests” may only be from a treating health care professional, i.e., recommending a test.
- Health plans can still promote health and appropriate testing through education of providers and patients.

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- Payment
 - Medical necessity still applies.
 - Genetic test can never be “required.”

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 - Patients need robust enforcement from all federal agencies. Not been the case recently.

Any questions?

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www.DNAPolicy.org

sbaruch2@jhu.edu