Current Privacy Legislation in US

The Common Rule

NIH Genomic Data Sharing Policy

Certificates of Confidentiality

Genetic Information Nondiscrimination Act (GINA)

Health Insurance Portability and Accountability Act (HIPAA)

The Freedom of Information Act (FOIA)

One problem with GINA that the Omnibus Rule perpetuates—and CalGINA does not address either—is that GINA is based on a genetics framework that is more than 20 years old.

If the presence of genetic markers is considered a "manifestation" of a disease, **then neither GINA nor HIPAA applies to the information.**


Protecting genetic information
privacy

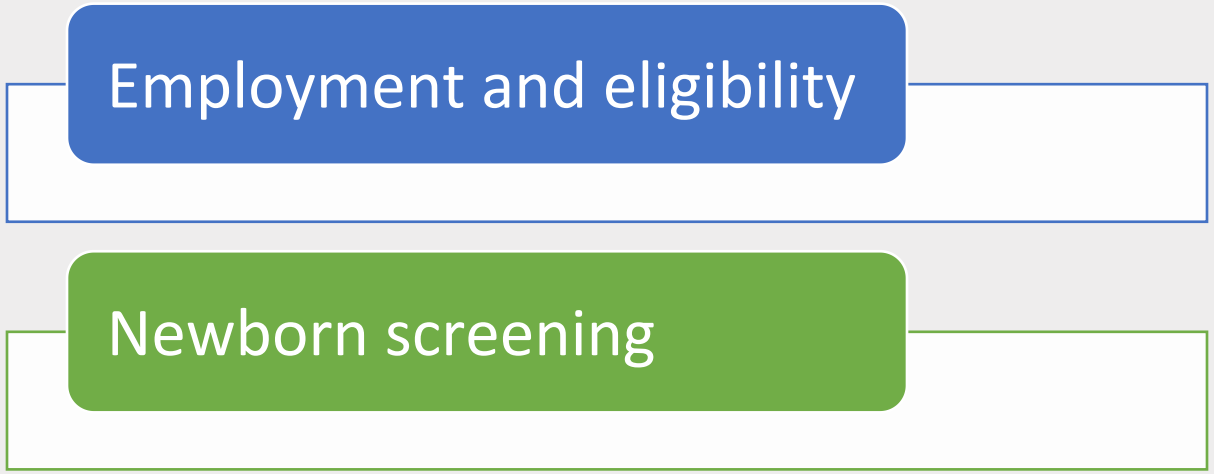
Protecting genetic information privacy

- With genetic data—or any personal health information (PHI)—it’s important to remember that HIPAA only applies to an organization if it is either a "covered entity" or the business associate (BA) of one.
- 23andMe Ancestry.com
- Food and Drug Administration (FDA)
- violation of the Federal Food, Drug and Cosmetic Act.
- "if the BRCA-related risk assessment for breast or ovarian cancer reports a false positive, it could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening, or other actions, while a false negative could result in a failure to recognize an actual risk that may exist."

Protecting genetic information privacy

- Obviously, existing laws that deal with genetic information fall short in many ways. One corrective approach to the limits of GINA and HIPAA—and not only where genetic information is concerned—would be to apply protections to the data itself, rather than making them dependent on who has the data. This dispenses with the patchwork created by "covered entities."

Some major unaddressed issues concerning genetic information privacy



Consent for Disclosure

- Finally, there is a complex ethical issue around the consent for disclosure of genetic information that contain DNA, for research purposes and otherwise. We're used to thinking of consent as individual, which makes sense when the health information is mainly about that person. Genetic information is different: analysis of an individual's DNA is highly informative about his or her offspring, siblings, and parents.
- The Supreme Court of Iceland, for instance, found in 2003 that a woman had a right to opt out of her father's genetic information being retained in Iceland's national DNA database. Genetic information also bears on demographic categorization, as many genetic predispositions toward specific diseases or conditions are strongly associated with specific ethnic or racial groups.