GINA REGULATIONS PROHIBIT COLLECTING GENETIC INFORMATION

The Genetic Information Nondiscrimination Act (GINA) of 2008 deals with the collection and use of genetic information by primarily employers and health insurance companies. The Equal Employment Opportunity Commission ("EEOC") published the final regulations related to GINA in late 2010 with an effective date of January 10, 2011.

Medical practices are impacted both as employers and as a source of providing genetic information to other employers from company sponsored physicals and to insurance companies.

GINA impact as an employer

The law states that employers:
* Must not discriminate in decisions related to hiring, firing, compensation and other terms of employment based on genetic information
* Must not request, require, collect or purchase genetic information on the employee, potential employee or their family. Some exceptions apply.
* Must maintain any genetic information about an employee or their family in a confidential medical record not in the employee personnel file.

There are occasions when an employer may need genetic information to comply with other Federal laws and there are exceptions that allow this. Genetic information may be needed:
* If an employer must have information to accommodate a disability of the employee
* If an employer needs information necessary to deal with a FLMA request

Information obtained voluntarily as a part of a wellness program is allowed with some exceptions. Specifically if the employee is not penalized for not providing the information, the employee provides an authorization form voluntarily and information given to the employer is in aggregate form, not specific to an employee.

Maintain secure medical files for employees if you have genetic information
Maintain genetic information in a separate medical file, not in the employees personnel file. Any genetic information in an employee file before November 21, 2009 can be left in the personnel file but all regulations on access to the information or providing copies still apply even if you leave the information in the file.

Unintentional access to genetic information is a violation in some cases.

An employer may violate GINA without intent by requesting information in a way that it is likely the employer will receive genetic information in response. For example:

* If a company requires a physical prior to employment and that physical documentation from the healthcare provider gathers genetic information that is then passed on to the employer, the employer could be in violation through no fault of their own.

* An employer may request information about a Workers Compensation claim that would include genetic information that may or may not be relevant to the claim in question.

- GINA specifically says an employer cannot request a person's complete medical record in circumstances that are exceptions because they are likely to contain information unrelated to the request – Workers Compensation or accommodation for a disability.

To prevent this unintentional access, the EEOC created a safe harbor for employers.

The employer must warn the healthcare provider not to provide genetic information in these cases. Without this warning the employer will be in violation if they receive the information.
The final rule includes the following language that a covered entity may use to provide notice to the healthcare provider to exclude genetic information: *''The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits employers and other entities covered by GINA Title II from requesting or requiring genetic information of employees or their family members. In order to comply with this law, we are asking that you not provide any genetic information when responding to this request for medical information. 'Genetic information,' as defined by GINA, includes an individual's family medical history, the results of an individual's or family member's genetic tests, the fact that an individual or an individual's family member sought or received genetic services, and genetic information of a fetus carried by an individual or an individual's family member or an embryo lawfully held by an individual or family member receiving assistive reproductive services.''*

Alternative language may also be used, as long as individuals and health care providers are informed that genetic information should not be provided.

The regulation 1635.8.d, states: "A covered entity must tell health care providers not to collect genetic information, including family medical history, as a part of a medical examination intended to determine the ability to perform a job and must take additional reasonable measures within its control if it learns that genetic information is being requested or required. Such measures may include no longer using the services of a healthcare professional who continues to request as a part of a medical examination."

HIPAA and GINA

If the employee gives you a HIPAA compliant authorization form you may release only the information defined.

What action may be required by healthcare providers? Take action as an employer and a healthcare provider that provides information to other employers.

As an employer

- Do not request genetic information from new employees or applicants.
- Remove all current genetic information from personnel files, at least back through November.
- Post the new EEOC posters informing employees

As a healthcare provider

- Assume that all companies have given you the required exclusion statement and exclude the gathering of genetic information.

- Many employers may not be aware of the law and you can help them by providing information to them about the law.

- Use a prefilled authorization form that states the exclusions or what is to be included to prevent employee error.

- Revise forms for a company physical.

- Determine if you, as a healthcare provider, needs to gather the information or not during the physical. What is your liability?

- Train all employees on action to take in releasing information to employers.

The GINA regulations and guidance can provide more detail on the intent of the law.