On May 21, 2008 President Bush signed into law the Genetics Information Nondiscrimination Act (GINA). This bi-partisan legislation establishes basic legal protections designed to encourage individuals to participate in genetic testing and new therapies that become available with advancements in science without fear that their genetic background will be used as a basis for discrimination. GINA prohibits plans and health insurers from adjusting premiums based on an individual’s predisposition to a genetic condition and prohibits employers from using or acquiring genetic information to influence their employment decisions. The legislation also prohibits any covered entity from requesting or requiring an individual or family member to submit to genetic testing. It remains to be seen whether the provisions of the Act will require changes in the way most employers conduct business, as few collect or use genetic information at present. Since employers may act as sponsors and/or as fiduciaries of a group plan, an employer may be susceptible to charges under either Title I or Title II of the Act depending on the nature of the alleged violation.

It should also be noted that the provisions of this Act will not preempt or state laws with equal or greater protection. At least 34 states have laws prohibiting genetic discrimination in the workplace and as of February 2007, 48 states had laws on genetic discrimination in insurance. Federal laws such as HIPAA and Title VII of the Civil Rights Act of 1964 also previously protected against some discriminatory practices against individuals on the basis of genetic information; this protection is expanded by GINA.

I. Definitions that apply to Title I and II

A. Genetic Information

As defined by GINA, “genetic information” includes the individual’s genetic tests, the genetic tests of family members of the individual, and the individual’s family medical history. Any information related to the individual’s or any family member’s participation in clinical research offering genetic services is included as is the genetic information of any fetus and embryo of an individual or family member of an individual who is pregnant. Information about the sex or age of the individual is not included.

The legislative history indicates that Congress did intend to draw a fine line between genetic information and general medical records. For example, individuals may still be requested to partake in physician evaluations and conduct lab work prior to enrollment. However, Congress did intend to circumscribe the ability of plans and issuers to use genetic information as part of this underwriting process. This Act prohibits genetic information from being used for adjusting insurance rates. Although the legislative history recognizes the difficulty behind isolating genetic
information from the general body of health information, future regulations may help to provide clearer and more workable standards.

B. Genetic Test

The Act defines “genetic test” to include any analysis of DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. A genetic test for purposes of Title I does not include any medical test to a current condition that can be detected by a reasonable physician. This exception does not apply to Title II, which prohibits employers from using genetic tests.

C. Genetic Services

“Genetic Services” is defined to include genetic tests, genetic counseling and genetic education.

II. Effect on Other Laws.

Title I amends provisions in ERISA, the Public Health Service Act, and the Social Security Act to specify prohibitions against the use or disclosure of genetic information in group and individual health insurance markets. In addition, Title I amends HIPAA regulations to extend privacy protections to the use and disclosure of genetic information. GINA functions as the federal floor to the protection of genetic rights and does not pre-empt other federal and state laws that provide equal or more protection.

**TITLE I: HEALTH INSURANCE**

I. Coverage and Effective Date:

Before GINA, there were no federal nondiscrimination protection laws enforced against the individual health insurance market. Effective May 21, 2009, GINA applied to employer-sponsored group health plans, health insurance issuers offering health insurance coverage in the group and individual markets, and Medigap insurance. State and local non-federal governmental plans, including plans with less than two participants and retiree-only plans, are also covered. Title I affects health insurance underwriting practices and eligibility requirements but is not designed to regulate medical care and treatment. The Secretaries of Labor and Health and Human Services who are charged with enforcement of this Title are to promulgate final regulations before the effective date of the Act.

II. Prohibited Insurance Practices

A. No Discrimination on Premium Rates

It is unlawful for any plan or issuer to adjust premium or contribution amounts on the basis of “genetic information”. For example, a plan may not increase an individual’s premium amount because the individual’s record reveals that he is predisposed to developing Huntington’s Disease or on the basis that the individual’s family member participated in a genetic test for Tay
Sach’s disease. However, GINA does not limit the ability of a plan or issuer from adjusting premiums based on a manifestation of a disease or disorder for an individual already enrolled in a plan.

Underwriting for manifested conditions is still a permitted practice after GINA. Nothing in the Act prohibits a plan or issuer from taking account of the health of each member enrolled in the group to set or renew premium rates for the group as a whole. For example, if an individual holds a family health policy and his son is tested positive for cystic fibrosis using a metabolic test directly related to a manifested condition, this Act does not bar the insurance company from raising premiums for the family’s health insurance. However, a manifested condition in one individual cannot be used as “genetic information” about other individuals.

B. Limitations on Genetic Testing

It is a prohibited insurance practice for a plan or issuer to request or require an individual or a family member of the individual to undergo genetic testing. However, this provision does not interfere with the ability of a health care provider to request an individual or family member to participate in genetic services. Health care providers who are affiliated with a group health plan are permitted to notify the individual of genetic testing and provide relevant information. It is important to note that this Act was not intended to interfere with the relationship between the physician and the patient. Regardless of whether the physician is in private practice or employed by a health plan, a physician may request a patient to undergo genetic testing.

In addition, nothing in this provision prevents a plan or issuer to provide information about genetic testing to health care professionals nor does it limit the documentary evidence that a plan or issuer may require to verify payment for a claim. For example, a health insurance company may require documentation that a patient did undergo genetic testing and the results of the test may be used to calculate the payment so long as the minimum amount of information is requested to accomplish the objective.

GINA also provides for a research exception. A covered entity may request an individual to participate in genetic testing if the following conditions are met: (1) the request is in writing; (2) participant understands compliance is voluntary; (3) acquired genetic information will not be used for underwriting purposes; (4) the appropriate Secretary is notified; and (5) the plan or issuer complies with any other conditions the Secretary imposes.

C. Prohibition on the Collection of Genetic Information

No covered entity may request, require, or purchase genetic information for purposes of underwriting. The legislative history suggests that since insurance companies are banned from using genetic information to adjust rates or determine eligibility, Congress also intended to limit the ability of plans and insurers to collect the information in the first place.

However, it is not a violation to inadvertently collect genetic information. Examples in the legislative history include instances where the plan or issuer acquires “genetic information” that an individual offered voluntarily as part of a general health application. However, if that
information is not requested or required, and the plan or issuer does not use the acquired information in a discriminatory way, there is no violation.

III. Enforcement

With respect to nondiscrimination requirements, violators of the Act may be subject to minimum penalties of $100 per day of non-compliance with a minimum penalty of $2500. A higher minimal penalty of $15,000 will be substituted in cases where the violation is not de minimus.

With regards to the privacy provisions that are enforced by the HHS Office of Civil Rights, any violations may be punishable by up to $250,000 and 10 years in prison, if the violations are committed for commercial advantage, personal gain, or malicious harm. Penalties may be waived where reasonable diligence was observed by the entity and the failure is corrected within a 30-day period starting from the first day of non-compliance. Any person alleging discrimination on the basis of genetic information may bring a private lawsuit whereby a court may award equitable relief by retroactively applying coverage or applying an administrative penalty.

TITLE II: EMPLOYMENT PROVISIONS

I. Coverage and Effective Date

Title II of GINA took effect in November, 2009 and applies to employers, unions, employment agencies, labor-management training programs and any other entity to which the Civil Rights Act of 1964 applies. The Act requires Equal Employment Opportunity Commission (EEOC) to issue interpretive regulations no later than one year after the date of enactment. At this time, there is only a cause of action for disparate treatment (intentional) violations of the Act. However, the Act calls for a study commission to be created six years from now to review the issue of whether there should be a cause of action under GINA for disparate impact.

II. Prohibited Employment Practices

A. Prohibition on the “Use” of Genetic Information

Title II prohibits covered employers or agencies from using genetic information to discriminate against any employee with respect to compensation, terms, conditions, or privileges of employment. This includes but is not limited to decisions concerning hiring new employees, firing, job assignments, and promotions. Thus, for example, it would be unlawful for an employer to discharge an otherwise healthy applicant because of a fear that the employee may develop breast cancer given the employee’s family medical history. The ban on discrimination also applies to any employment practice that uses genetic information to limit or classify employees in any way that would deprive the employee of an employment opportunity or adversely affect their employment status in any way. In addition to the prohibited employment practices discussed above, employment agencies or training programs are also forbidden from causing an employer to discriminate against an individual on the basis of the individual’s genetic information.
B. Prohibition on Collection of Genetic Information

No employer or agency may request, require, or purchase genetic information about an employee or family member except under limited circumstances.

The first exception addresses situations where the employer unintentionally is made aware of the employee’s family medical history through casual conversations at work (the so-called “water cooler” problem). The second exception protects the employer from liability for requesting any genetic information as part of the employer’s voluntary wellness program. However, any genetic information obtained must still be subject to confidentiality and cannot be disclosed to the employer except in aggregate non-individually identifiable terms. The third exception allows an employer to acquire genetic information to comply with provisions of state and federal family and medical leave laws. The fourth exception excuses employers from liability if they receive family medical history from published documents including newspapers, magazines, periodicals or books. This does not include medical databases or court records. The fifth exception, which is subject to certain qualifications, allows employers to obtain genetic information for the purpose of conducting genetic monitoring of toxic substances in the workplace. Lastly, forensic laboratories may collect information for quality control purposes. It should be noted that although there are instances where an employer is permitted to acquire genetic information, the information may not be used to discriminate against any employee.

C. Privacy Limitations

Title II is consistent with the ADA rules in requiring that genetic information acquired be filed separately and treated as part of the employee’s confidential medical records. Disclosure is prohibited unless it is to the individual, an occupational or health researcher or a government official investigating a violation of this Act. In addition, an employer may disclose an employee’s genetic health record if it is done in compliance with federal regulations, federal or state medical leave laws or with a court order.

III. Enforcement

The employment title of GINA is enforced by the EEOC and the Attorney General. Any person alleging a violation of the Act may file a private lawsuit. Compensatory and punitive damages will be awarded according to the same structure as Title VII (including the statutory caps). Individuals still remain free to seek relief for violations under the ADA, the Rehabilitation Act or GINA but double recovery for the same facts or occurrence is not allowed.

RETLATION PROHIBITED

The Act prohibits any retaliation by a covered entity against persons who oppose practices or acts made unlawful by any provision in this Act or because the individual made a charge or participated in making a charge in any proceeding under the Act.
CHILD LABOR PENALTIES INCREASED

In order to offset its funding, GINA amends the Fair Labors Standard Act to increase the penalty from $10,000 to $11,000 per child labor violation. In addition, the bill includes a provision that allows the Labor Department to assess civil penalties up to $50,000 when a violation results in death or serious injury. Up to a $100,000 penalty may be charged for repeat violations. The penalty increases are estimated to produce $1 million annually.

CONCLUSION

GINA approaches genetic discrimination based on an approach known as genetic exceptionalism which treats genetic information distinctly from general health information. This Act expansively defines what can be considered “genetic information” to include an individual’s family medical history and represents an affirmative step towards declaring a national policy against using genetic information to discriminate against individuals in both insurance and employment.