

Protecting the Privacy of Genetic Information

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Advances in the study of human genetics and predictive genetic technologies, most notably the mapping of the human genome, have led to an increased understanding of how genetic code might relate to future health outcomes. These insights have raised concerns relating to the privacy of genetic information. The question becomes, what privacy protections does the law afford to individual persons and their genetic code, and how might the law protect individuals from discrimination when their privacy is violated?

Many states have passed genetic privacy laws of their own, given the prior absence of overriding federal legislation, and the variable scope and provisions of these laws is testament to the complexity of the issue. It is with an understanding of these laws — particularly the implications for employers or insurers — that businesses might best understand their rights, responsibilities, and potential liabilities as they relate to the collection, dissemination, and application of genetically derived employee or enrollee data. While the federal government just passed comprehensive legislation, it does not preempt state law, so higher state restrictions must also be met.

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GENETIC PRIVACY: GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008

President Bush just signed the Genetic Information Nondiscrimination Act of 2008, also known as “GINA.” GINA modifies a number of existing laws, as well as adding a number of new laws to the United States Code. As with existing state law discussed below, the law contains limitations on the use of genetic testing for certain insurance purposes, including underwriting and premium adjustments, and also restricts the use of genetic testing by insurers. These restrictions are contained in modifications to ERISA, as well as other sections of the United States Code, and they are applicable to group health plans and health insurers, insurers offering insurance to individuals, medigap insurers, as well as other insurers.

GINA also changes several aspects of HIPAA, and there are to be changes to the definitions under the HIPAA privacy rule to include genetic information, as well as new definitions regarding genetic testing.

Employers are also restricted in what information they can obtain from employees. Subject to certain exceptions, employers cannot request, require, or purchase genetic information regarding an employee, or a family member. There are also specific genetic privacy restrictions on genetic information that is collected by employers. The restrictions on employers are also applicable to government employees.

While portions of the law are effective in the near term, other portions are not effective for up to 18 months. Additionally, there are a number of rule changes that must occur, including changes to HIPAA, and additional regulations that must be generated.

GENETIC PRIVACY: PROTECTIONS TO THE FEDERAL DNA INDEX

The Combined DNA Index System (“CODIS”)¹ is a federally funded computer system which contains identifying DNA records or analyses of:

- Persons convicted of crimes,

- Persons who have been charged in an indictment or information with a crime,
- Persons whose DNA samples are collected under the jurisdiction of applicable legal authorities,²
- Analyses of DNA samples recovered from crime scenes,
- Analyses of DNA samples recovered from unidentified human remains, and
- Analyses of DNA samples voluntarily contributed from relatives of missing persons,³ so long as the records and analyses were performed by or on behalf of a criminal justice agency, or in accordance with other proscribed federal standards, for the purposes of law enforcement.

It should be noted that DNA samples that are voluntarily submitted solely for the purposes of eliminating a subject from suspicions in an investigation cannot be included in CODIS.⁴

The fact that CODIS contains specifically identifying genetic records is unique. Generally speaking, federal regulations forbid the collection and storage of identifying DNA records or biological materials without express informed consent from the sample donors. Nonetheless, in the absence of overarching federal legislation for the protection of genetic information, a discussion of how privacy is preserved in the index is instructive.

Privacy Protections for Individuals in CODIS

The integrity of CODIS is preserved through inclusion and disclosure limitations. The index can only include information on DNA identification records and DNA analyses that are based on analyses performed by or on behalf of a criminal justice agency (or the Secretary of Defense in accordance with 10 U.S.C. §1565) in accordance with specified standards.⁵

Also, the law places restrictions on the use of results of DNA tests. Specifically, the results of CODIS DNA records and analyses may be disclosed only:

- To criminal justice agencies for law enforcement identification purposes;

- In judicial proceedings,
- If otherwise admissible pursuant to applicable statutes or rules; or
- For criminal defense purposes, to a defendant, who must have access to samples and analyses performed in connection with the case in which such defendant is charged.⁶

If results are de-identified, they may be disclosed for a population statistics database, for identification research and protocol development purposes, or for quality control purposes.⁷

Expungement of Records

There are two circumstances in which the Director of the FBI must clear the DNA analysis of a person from CODIS:

- If the original placement in the index was based upon a conviction for a qualifying Federal offense⁸ or a qualifying District of Columbia offense, the Director must expunge the record if the Director receives, for each conviction of the person of a qualifying offense, a certified copy of a final court order establishing that the conviction has been overturned.⁹
- If the original placement was due to an arrest under the authority of the United States, the Director must expunge the record if the Attorney General receives, for each charge against the person on the basis of which the analysis was or could have been included in the index, a certified copy of a final court order establishing that such charge has been dismissed or has resulted in an acquittal or that no charge was filed within the applicable time period.¹⁰

Similar expungement requirements apply to the states as well.¹¹

STATE GUIDANCE: PRIVACY PROTECTION AND ISSUES OF DISCRIMINATION

It is instructive to observe how federal regulations protect the privacy

of individuals whose genetic records are indexed in CODIS, as it offers potential insight into what standards federal regulators might apply beyond the boundaries of the criminal justice system. Nonetheless, there are currently no overarching federal statutes to ensure that identifying genetic information collected outside of CODIS remains private. This becomes of particular concern when considered in the context of fears of genetic discrimination.

As of the date this publication was written, 32 states have enacted laws dealing directly with genetic privacy issues. The breadth of those laws varies significantly between states — some span several subsections of state code; others occupy a single paragraph. A review of these laws reveals three primary areas of enforcement:

- Prohibitions on the administration of genetic tests, or the collection of genetic materials, without informed consent;
- Requirements for and restrictions on disclosure of information obtained from genetic tests — that results be available to tested individuals and not disclosed to third parties without proper authorization; and
- Destruction or de-identification of materials after their purpose as test materials has been served.

But perhaps the most pressing concern for individuals is the issue of genetic discrimination, and the resultant loss of health insurance or employment based on a patient's genetic profile. Genetic discrimination therefore becomes an area of great liability for employers and insurers.

Several states address the issue of genetic discrimination within their statutes directly by expressly prohibiting insurers from denying policy or altering existing policy on the basis of the results of a genetic test or on the refusal or desire to undergo genetic testing. Some states also forbid employers from making any employment decisions based on genetic data.

The insurance and employment related provisions of three state genetic privacy acts will be discussed here. The language of this article does not reflect the entirety of the statutory texts and should not be taken for legal guidance. Rather, this intends to present an illustrative discussion of the

tensions that underlie the genetic privacy legislative landscape, as well as general rules by which privacies might be protected and liabilities avoided.

Idaho: Genetic Testing Privacy Act (Idaho Code Ann. § 39-8301-8304)

Except as otherwise provided, an employer cannot, in connection with a hiring, promotion, retention, or other related decision:

- Access or otherwise take into consideration private genetic information about an individual that would be otherwise unavailable in a routine, exam such as a physical exam or urine test;
- Request or require an individual to consent to a release of personal and private genetic information;
- Request or require an individual or his blood relative to submit to a genetic test; or
- Question the individual or blood relatives' motives regarding their decision to have taken or their refusal to have taken a genetic test.

However, an employer is permitted to seek an order compelling disclosure of private genetic information under certain circumstances, in connection with an employment-related judicial or administrative proceeding in which the individual has placed his health at issue, or an employment-related decision in which the employer has a reasonable basis to believe that the individual's health condition poses a real and unjustifiable safety risk requiring the change or denial of an assignment.

Idaho insurance law also states, it is illegal for a person to discriminate on the basis of a genetic test or private genetic information in the issuance of coverage, or the fixing of rates, terms or conditions, for any policy or contract of disability insurance or any health benefit plan.

Louisiana (La. Rev. Stat. Ann. § 213.7)

Louisiana genetic privacy law, on the subject of employer and insurer practices, is particularly comprehensive.

Under Louisiana state law (La. Rev. Stat. Ann § 213.7) it is illegal for an insurer to, on the basis of any genetic information concerning an individual or family member or on the basis of an individual's or family member's request for or receipt of genetic services, or the refusal to submit to a genetic test or make available the results of a genetic test:

- Terminate, restrict, limit, or otherwise apply conditions to the coverage of an individual or family member under the policy or plan, or restrict the sale of the policy or plan to an individual or family member;
- Cancel or refuse to renew the coverage of an individual or family member under the policy or plan;
- Deny coverage or exclude an individual or family member from coverage under the policy or plan;
- Impose a rider that excludes coverage for certain benefits or services under the policy or plan;
- Establish differentials in premium rates or cost sharing for coverage under the policy or plan; or
- Otherwise discriminate against an individual or family member in the provision of insurance.

It is illegal for an insurer to require an applicant for coverage under the policy or plan, or an individual or family member who is presently covered under a policy or plan, to be the subject of a genetic test or to be subjected to questions relating to genetic information.

Also, insurers are required to give applicants or enrollees clear and conspicuous notice of these rights, in the application or enrollment information provided by the insurer concerning a policy or plan.

Furthermore, an insurer also cannot obtain genetic information from an insured or enrollee, or from their DNA sample, without first obtaining valid and written informed consent. To be valid, an authorization for disclosure of genetic information must:

- Be in writing, signed by the individual and dated on the date of such signature;

- Identify the person permitted to make the disclosure;
- Describe the specific genetic information to be disclosed;
- Identify the person to whom the information is to be disclosed;
- Describe with specificity the purpose for which the disclosure is being made;
- State the date upon which the authorization will expire, which in no event shall be more than 60 days after the date of the authorization;
- Include a statement that the authorization is subject to revocation at any time before the disclosure is actually made or the individual is made aware of the details of the genetic information; and
- Include a statement that the authorization shall be invalid if used for any purpose other than the described purpose for which the disclosure is made.

A copy of the authorization must be provided to the individual and it can be revoked or amended at any time. It should be noted that an authorization for the release of medical records or medical information shall not be construed as an authorization for disclosure of genetic information, although the privacy restrictions in this law do apply to medical records that contain genetic information.¹²

Finally, Louisiana law makes an insured's or enrollee's genetic information the property of the insured or enrollee, and thus the law restricts a third party from retaining an insured's or enrollee's genetic information without first obtaining authorization from the insured, enrollee, or their representative, unless the retention is:

- For the purposes of a criminal or death investigation or for use in a criminal or juvenile proceeding; or
- To determine paternity.

One notable point here, of course, is not the requirement of authorization for release but rather the treatment of genetic information as being the property of the insured or enrollee.

It should also be noted that this law does not apply to any actions of an insurer or third parties dealing with an insurer taken in the ordinary course of business in connection with the sale, issuance, or administration of a life, disability income, long-term care, or critical illness insurance policy. In those ordinary courses, such insurers or third parties would be exempt from the provisions of this law.

Texas (Tex. Lab. Code Ann. § 21.402-404; Tex. Occ. Code Ann. § 58; Tex. Ins. Code Ann. § 546)

Texas law has specific provisions that attempt to prevent discrimination on the basis of genetic information. For example:

An employer, labor organization, or employment agency commits an unlawful employment practice if the employer, labor organization, or employment agency limits, segregates, or classifies an employee, member, or applicant for employment or membership in a way that would deprive or tend to deprive the employee, member, or applicant of employment opportunities or otherwise adversely affect the status of the employee, member, or applicant on the basis of genetic information concerning the employee, member, or applicant, or because of the refusal of the employee, member, or applicant to submit to a genetic test.¹³

A licensing authority may not deny an application for an occupational license, suspend, revoke, or refuse to renew an occupational license, or take any other disciplinary action against a license holder based on the refusal of the license applicant or license holder to: submit to a genetic test; submit a family health history; disclose whether the applicant or holder has submitted to a genetic test; or disclose the results of any genetic test to which the applicant or holder has submitted.¹⁴

The regulations pertaining to insurers, listed below, apply only to a health benefit plan that provides certain benefits.¹⁵ There are certain exceptions for plans that provide certain forms of coverage.¹⁶

A health benefit plan issuer that requests an applicant for coverage under the plan to submit to a genetic test in connection with the application for coverage for a purpose not prohibited by statute must adhere to certain requirements of informed consent and communication of test

results. A health benefit plan issuer may not use the results of a genetic test conducted in accordance with the requirements above to induce the purchase of coverage under the plan.¹⁷

Furthermore, a health benefit plan issuer may not use genetic information¹⁸ or the refusal of an applicant to submit to a genetic test to reject, deny, limit, cancel, refuse to renew, increase the premiums for, or otherwise adversely affect eligibility for or coverage under the plan.¹⁹

Also, it is illegal for a health benefit plan issuer to require as a condition of coverage genetic testing of a child in utero without the pregnant woman's consent, or use genetic information to coerce²⁰ or compel a pregnant woman to have an induced abortion.²¹

GENETIC PRIVACY ISSUES IN LITIGATION

There exists little precedent today that directly addresses issues of genetic privacy. In one of the first cases to address genetic privacy, the Supreme Court in Washington concluded that there was no inherent right of privacy in discarded genetic information that was used for purely identification purposes, even where the police obtained the sample through deception.²² However, the courts have yet to address specifically the issues of genetic privacy in the workplace and genetic discrimination.

A clear understanding of how the federal and state regulations currently address issues of genetic privacy will be invaluable to avoiding potential liabilities later on.

NOTES

¹ 42 U.S.C. § 14135a(a)(3).

² 42 U.S.C. § 14132(a)(1)(A)-(C).

³ 42 U.S.C. § 14132(a)(2)-(4).

⁴ 42 U.S.C. § 14132(a)(1)(C).

⁵ 42 U.S.C. § 14132(b)(1)-(2)(A)-(B).

⁶ 42 U.S.C. § 14133(b)(1)(A)-(C).

⁷ 42 U.S.C. § 14133(b)(2).

⁸ The term "qualifying offense" means any of the following offenses: (i) A qualifying Federal offense, as determined under § 14135a of this title. (ii) A

qualifying District of Columbia offense, as determined under § 14135b of this title. (iii) A qualifying military offense, as determined under 10 U.S.C. § 1565. 42 U.S.C. 14132(d)(1)(B)(i)-(iii).

⁹ 42 U.S.C. § 14132(d)(1)(A)(i).

¹⁰ 42 U.S.C. § 14132(d)(1)(A)(ii).

¹¹ 42 U.S.C. § 14132(d)(2)(A)(i)-(ii).

¹² La. Rev. Stat. Ann. § 213.7(C)(5).

¹³ Tex. Lab. Code Ann. § 21.402(d)(1)-(2).

¹⁴ Tex. Occ. Code Ann. § 58.051(1)-(4).

¹⁵ This includes one that (1) provides benefits for medical or surgical expenses incurred as a result of a health condition, accident, or sickness, including: (A) an individual, group, blanket, or franchise insurance policy or insurance agreement, a group hospital service contract, or an individual or group evidence of coverage that is offered by: (i) an insurance company; (ii) a group hospital service corporation operating under Chapter 842; (iii) a fraternal benefit society operating under Chapter 885; (iv) a stipulated premium company operating under Chapter 884; or (v) a health maintenance organization operating under Chapter 843; and (B) to the extent permitted by the Employee Retirement Income Security Act of 1974 (29 U.S.C. Section 1001 et seq.), a health benefit plan that is offered by: (i) a multiple employer welfare arrangement as defined by Section 3 of that Act; (ii) another entity not authorized under this code or another insurance law of this state that directly contracts for health care services on a risk-sharing basis, including a capitation basis; or (iii) another analogous benefit arrangement; or (2) is offered by an approved nonprofit health corporation that holds a certificate of authority under Chapter 844. Tex. Ins. Code Ann. § 546.002(1)-(2).

¹⁶ It does not apply to: (1) a plan that provides coverage: (A) only for a specified disease; (B) only for accidental death or dismemberment; (C) for wages or payments in lieu of wages for a period during which an employee is absent from work because of sickness or injury; or (D) as a supplement to liability insurance; (2) a Medicare supplemental policy as defined by Section 1882(g)(1), Social Security Act (42 U.S.C. Section 1395ss); (3) workers' compensation insurance coverage; (4) medical payment insurance coverage provided under a motor vehicle insurance policy; or (5) a long-term care policy, including a nursing home fixed indemnity policy, unless the commissioner determines that the policy provides benefit coverage so comprehensive that the policy is a health benefit plan as described by § 546.002. Tex. Ins.

Code Ann. § 546.032(1)-(5).

¹⁷ Tex. Ins. Code Ann. § 546.051(c).

¹⁸ “Genetic information” means information that is: (A) obtained from or based on a scientific or medical determination of the presence or absence in an individual of a genetic characteristic; or (B) derived from the results of a genetic test performed on an individual. § 546.001(3). “Genetic characteristic” means a scientifically or medically identifiable genetic or chromosomal variation, composition, or alteration that predisposes an individual to a disease, disorder, or syndrome. Tex. Ins. Code Ann. § 546.001(2).

¹⁹ Tex. Ins. Code Ann. § 546.052.

²⁰ In this section, “coerce” means to restrain or dominate a woman’s free will by actual or implied: (1) force; or (2) threat of rejecting, denying, limiting, canceling, refusing to renew, or otherwise adversely affecting eligibility for coverage under a health benefit plan. Tex. Ins. Code Ann. § 546.053(a)(1)-(2).

²¹ Tex. Ins. Code Ann. § 546.053(b)(1)-(2).

²² See *State of Washington v. Athan*, 160 Wash. 2d 354 2007.