

Legal Updates & News

Legal Updates

New Federal Law Regulates Collection and Use of Genetic Information by Employers and Group Health Plans

May 2008

by [Marian A. Waldmann](#), [Timothy G. Verrall](#), [Christine E. Lyon](#)



Related Practices:

- [Employee Benefits and Executive Compensation](#)
- [Employment and Labor](#)
- [Privacy and Data Security](#)
- [Tax](#)

On May 21, 2008, President Bush signed into law the Genetic Information Nondiscrimination Act of 2008 (“GINA” or the “Act”).^[1] GINA prohibits employers and group health plans from discriminating on the basis of “genetic information,” and strictly limits the collection of such information by employers and group health plans. Significantly, “genetic information” includes not only the results of genetic tests, but also covers information about an individual’s family medical history. Employers and group health plans may be liable under GINA for unlawful collection of genetic information, even if no discrimination is alleged. Conversely, employers and group health plans may be liable under GINA for unlawful discrimination, even if they can establish a lawful basis to possess the genetic information. Due to GINA’s broad definition of “genetic information,” this law will affect all employers and group health plans, regardless of whether they use genetic testing.

The requirements imposed by the Act in the employment context will enter effect in October 2009 and the requirements for group health plans and health insurers will generally enter effect on January 1, 2010.

Scope of “Genetic Information” Covered by GINA

“Genetic information” is defined as information about (1) an individual’s genetic tests,^[2] (2) genetic tests of the individual’s family members and (3) the “manifestation of a disease or disorder” in the individual’s family members.^[3] Notably, the last category is not limited to information about hereditary medical conditions—nor is it limited to information about the medical conditions of biological relatives.

Under GINA, “family members” include a dependent and “any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual or such individual’s dependent.”^[4] The legislative history explains that GINA “applies to spouses and adopted children of an individual because of the potential discrimination an employee...could face because of an employer’s or other entities’ concern over potential medical or other costs and their effect on insurance rates.”^[5] Accordingly, GINA appears to prohibit discrimination based on the family medical history of an individual’s dependent, even if the individual does not share the same family medical history.

New Restrictions on Employers

GINA is hardly the first U.S. law to regulate genetic testing or discrimination in the employment context. At least 34 states and the District of Columbia have already passed laws prohibiting some form of genetic discrimination in employment.^[6] GINA does not preempt or limit more protective state and federal employment laws.^[7] However, GINA is broader than many of the existing laws,

particularly with respect to its coverage of information about an individual's family medical history.

The Act imposes three categories of restrictions on employers: (1) it prohibits employers from discriminating on the basis of genetic information; (2) it restricts an employer's acquisition of genetic information; and (3) and it requires employers to take specific measures to maintain the confidentiality of genetic information. These restrictions apply to public- and private-sector employers, employment agencies, labor organizations^[8] and training programs.^[9]

Discrimination Prohibited

GINA adds "genetic information" as a protected characteristic under Title VII of the Civil Rights Act of 1964, which prohibits discrimination based on race, color, religion, sex, national origin or other specified characteristics.^[10] Employers, employment agencies, labor organizations and training programs are each restricted from discriminating against an employee or member in a way that would limit, segregate or classify individuals so as to deny any individual an employment opportunity or adversely affect the individual's status as an employee.^[11] Additionally, GINA prohibits the following types of employment-related discrimination:

- Employers are prohibited from discriminating based on genetic information when hiring or firing an individual or with respect to compensation, terms, conditions and privileges of employment.
- Employment agencies are prohibited from failing or refusing to refer the individual for employment because of genetic information or otherwise discriminating against an individual based on his or her genetic information. Employment agencies are also prohibited from causing or attempting to cause an employer to discriminate against an individual based on his or her genetic information.
- Labor organizations are prohibited from excluding or expelling a member from membership because of genetic information or otherwise discriminating against any member based on his or her genetic information. Labor organizations are also prohibited from causing or attempting to cause an employer to discriminate against a member based on his or her genetic information.
- Training programs are prohibited from discriminating by refusing admission to, or employment in, any program established to provide apprenticeship, training or retraining, based on an individual's genetic information.

GINA prohibits any person from retaliating against an individual for filing a claim of genetic information discrimination.^[12]

Restrictions on an Employer's Acquisition of Genetic Information

GINA generally prohibits an employer from requesting, requiring or purchasing genetic information related to an employee or his/her family members,^[13] subject to the following limited exceptions (or "safe harbors"):

- *Inadvertent Requests of Genetic Information.*^[14] This exception applies when an employer "inadvertently requests or requires family medical history of the employee or family member of the employee." The legislative history explains that this exception was intended to address the "so-called 'water cooler problem,'" in which an employer may unintentionally elicit information about family health or medical history through "casual conversations" in the workplace.^[15]
- *Employee Wellness Programs.*^[16] This exception is intended to preserve employer-sponsored wellness programs by allowing the employer's receipt of genetic information where:
 - the employer offers health or genetic services, including as part of a wellness program;
 - the individual provides prior, knowing, voluntary *and* written authorization;
 - only the individual receiving genetic services and the licensed health care service provider receives individually identified results of such services; and
 - the employer receives information about such services only in aggregate terms that do not disclose the identity of specific employees.
- *Requests for Family Medical Leave.*^[17] This exception allows an employer to request family medical history to comply with the certification provisions of the Family and Medical Leave Act or similar state family or medical leave laws.
- *Purchase of Commercially and Publicly Available Documents.*^[18] This exception applies when an employer purchases documents that are commercially and publicly available, such as newspapers or magazines, which include family medical history. For example, the

legislative history indicates that this exception should apply when an employer purchases a local newspaper containing the obituary of an employee's parent who died of breast cancer.

[19] This exception does not apply to the purchase of medical databases or court records.

[20]

- *Genetic Monitoring of Biological Effects of Workplace Toxins.*[21] This exception allows an employer to conduct genetic monitoring[22] of the biological effects of toxic substances in the workplace, but only if:
 - the employer provides written notice of the genetic monitoring to the employee;
 - the employee provides prior, knowing, voluntary and written authorization or genetic monitoring is required by law;
 - the employee is informed of the individual genetic monitoring results;
 - the monitoring is in compliance with federal or state genetic monitoring regulations, such as regulations issued under the Occupational Safety and Health Act, the Federal Mine Safety and Health Act or the Atomic Energy Act; and
 - the employer, excluding any licensed health care professional or board certified genetic counselor involved in the genetic monitoring program, receives the monitoring results only in aggregate terms that do not disclose the identity of specific individuals.
- *Law Enforcement Purposes.*[23] This narrow exception applies when an employer conducts DNA analysis for law enforcement purposes as a forensic laboratory. Such an employer may require its employees to provide genetic information, but only to the extent that this information is used for analysis of DNA identification markers for quality control, to detect sample contamination.

Even if genetic information is legally acquired, it may not be used for discriminatory purposes or in violation of the Act's confidentiality requirements.[24]

Confidentiality Requirements

Even if an employer is allowed to possess genetic information under one of the foregoing safe harbors, the Act requires the genetic information to be maintained as a confidential medical record under the Americans with Disabilities Act ("ADA"). The ADA requires that confidential medical records be (i) collected on forms and maintained in files separate from the forms and files used to collect and maintain other employment-related information; and (ii) protected from unauthorized access.[25] The ADA limits access to confidential medical information by only allowing for the disclosure of confidential medical records (i) regarding necessary restrictions on work or duties and necessary accommodations for the employee to supervisors and managers; (ii) to first aid and safety personnel if the disability might require emergency treatment; and (iii) to government officials investigating compliance with the ADA.[26]

GINA further limits the disclosure of genetic information, providing that it can only be disclosed as follows:

- to the individual to whom the information relates at that individual's written request;
- to an occupational or other health researcher if research is in compliance with the regulations and protections of 45 C.F.R. 46, which addresses the protections for human research subjects;
- in response to a court order;[27]
- to government officials investing in compliance with this title;
- to the extent disclosure is made with employee's compliance with § 103 of the Family Medical Leave Act ("FMLA") or similar state family and medical leave laws; and
- to federal, state or local public health agency only with regard to the manifestation of a contagious disease in a family member that presents an imminent hazard of death or life threatening illness and the employee whose family member(s) are the subject of the disclosure is notified.

This Act does not prohibit a covered entity from any use or disclosure of health information authorized under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").[28] The use, acquisition or disclosure of medical information that is *not* genetic information about a manifested disease, disorder or pathological condition of an employee or member, even if the manifested disease, disorder or pathological condition has a genetic basis, will not be considered a violation of the Act.[29]

Remedies and Enforcement

The employment nondiscrimination provisions of GINA may be enforced in the same manner as

other discrimination claims under Title VII of the Civil Rights Act, including civil lawsuits and government enforcement actions by the Equal Employment Opportunity Commission (“EEOC”) or Attorney General.

The Act does not, however, establish a cause of action for disparate impact^[30] on the basis of genetic information. It provides that a Genetic Nondiscrimination Study Commission will be established in six years to review the developing science of genetics and make recommendations to Congress about whether the Act should be amended to provide a disparate impact cause of action.

Employers will receive further guidance about these new restrictions under GINA before they take effect. The Act provides that the EEOC will issue final regulations under GINA within the next year. The requirements imposed by the Act in the employment context will only become effective eighteen months from the date of enactment, in October 2009.

New Restrictions on Health Plans and Insurers

Prior to the adoption of the Act, federal law regarding the use of genetic information by group health plans and health insurers was limited to two sets of requirements under HIPAA. Among other things, HIPAA amended the Employee Retirement Income Security Act of 1974, as amended (“ERISA”), and the Internal Revenue Code of 1986, as amended (the “Code”), to (1) restrict the use of genetic information by group health plans as a basis for determining plan eligibility or the amount of employee contributions;^[31] and (2) restrict the use of genetic information by group health plans in applying preexisting condition limitations.^[32] HIPAA also amended the Public Health Service Act (“PHSA”) to impose similar limitations on health insurers operating in the group marketplace.^[33] However, these limitations did not preclude the use of genetic information to set group-wide insurance premiums, restrict the collection of genetic information by insurers, preclude mandatory genetic testing or limit the disclosure of genetic information nor did they generally apply in the individual insurance market.

The Act supplements HIPAA’s relatively narrow limitations on the use of genetic information in a number of key respects. The Act incorporates similar provisions into ERISA, the Code, and PHSA which are collectively applicable to group health plans with any number of participants and health insurance issuers underwriting the benefits offered by those plans.^[34] In addition, the Act imposes similar requirements on issuers of “MediGap” insurance policies.^[35] In broad terms, these provisions are intended to prevent group health plans and health insurers from imposing preemptive limitations on coverage or increased costs for individuals based on their genetic histories and potential predispositions towards particular illnesses and diseases.

Restrictions on Acquisition of Genetic Information and Discrimination Prohibited

The Act’s requirements include the following:

- Group health plans and health insurers may not set premiums or employee contribution levels based on genetic information.^[36]
- Mandatory genetic testing by group health plans or health insurers is prohibited.^[37]
- Group health plans and health insurers are prohibited from requesting, requiring or purchasing genetic information for underwriting purposes and may not seek such information from individuals who have not yet enrolled.^[38]

Title I of the Act includes defines “underwriting purposes” as rules for eligibility for coverage, computation of premiums or contribution amounts, application of preexisting condition limitations, and other activities relating to the creation, renewal or replacement of an insurance contract or health benefits.^[39]

The Act clarifies that genetic information can be used for the “payment” functions of a group health plan or health insurer.^[40] In addition, a health care provider is not precluded from requiring a genetic test as part of a course of treatment.^[41] Further, the Act creates an exception for research requests involving voluntary participation in genetic testing, provided certain disclosures are made to the test participants and the Departments of Labor, Treasury, and Health and Human Services and provided the results of the testing are not used for underwriting purposes.^[42]

The foregoing limitations extend not only to employees covered by a group health plan or insurance policy but also to their dependents and any of their first, second, third or fourth degree relatives.^[43] Genetic information relating to embryos and fetuses is expressly made subject to these limitations.

[44]

Remedies and Enforcement

Enforcement of the Act's requirements falls to the Department of Labor and IRS for group health plans and to the Department of Health and Human Services for health insurers.[45] Remedial provisions and penalties/excise taxes are substantially similar for each type of entity. Penalties and excise taxes of up to \$100 per day for each instance of noncompliance can be assessed against a group health plan; the penalty period runs from the date of the violation through the date it is corrected.[46] If a violation is not corrected prior to notice from the Department of Labor, the minimum penalty for each affected individual is \$2,500, but if the violations are more than de minimis, the minimum per-individual/per-violation penalty is \$15,000.[47] The penalty is not applicable where the violation would not have been discovered through the exercise of reasonable diligence and for inadvertent violations that are corrected within 30 days following discovery.[48] There is an overall cap on the collective penalty for unintentional violations equal to the lesser of 10% of the employer's costs for group health plans during the preceding year or \$500,000.[49] In each case, the respective regulators are given authority to fully or partially waive the penalty or excise tax for "good cause." [50]

The remedial provisions applicable to health insurers are based on the Secretary of Health and Human Services' existing enforcement authority under PHSA.[51]

The requirements imposed by the Act are generally effective for group health plans and health insurers beginning on January 1, 2010.[52] The Department of Labor (for ERISA), Secretary of Health and Human Services (for PHSA), and the Treasury (for the Code) are directed to issue final regulations under GINA within 12 months of the Act's enactment.

Other Noteworthy Issues Under GINA

GINA concludes with "miscellaneous provisions," which increase the penalties for violations of the child labor protections of the Fair Labor Standards Act. These provisions increase the general penalty for child labor violations from \$10,000 to \$11,000 for each employee who was the subject of a violation, and add a new penalty of \$50,000 for each such violation that causes the death or serious injury of any employee under the age of 18.[53] That new \$50,000 penalty can be doubled if the violation is a repeated or willful violation. These provisions also increase the penalty for repeated or willful wage violations from \$1000 to \$1100 per violation.[54]

Recommendations

GINA provides a nationwide, baseline level of protection from genetic discrimination. Unfortunately, since it does not preempt more protective laws, regulated entities must still know and comply with applicable state laws. Prior to the law's effective date, employers and group health plans should (1) examine how they collect genetic information, such as information about family medical history; (2) identify which exemptions may apply to their collection practices; and (3) analyze whether their current practices comply with the Act's confidentiality provisions with respect to any genetic information they currently maintain.

Additionally, employers and group health plans should continue to maintain careful documentation of their legitimate, nondiscriminatory reasons for taking adverse actions, to defend against potential lawsuits claiming genetic information discrimination. Because the definition of genetic information broadly includes a manifestation of a disease or disorder in a family member, employers and group health plans may receive an individual's genetic information in a variety of different contexts. Such entities should consider updating their practices to limit their collection of genetic information and thereby decrease their potential exposure to genetic discrimination claims.

Footnotes:

[1] Genetic Information Nondiscrimination Act of 2008, H.R. 493, 110th Congress (2008) (enacted) [hereinafter GINA].

[2] Under GINA, a "genetic test" includes any analysis of human DNA, RNA, chromosomes, proteins or metabolites that detects genotypes, mutations or chromosomal changes. Tests that do not detect abnormalities and those that are directly related to manifested disease or disorder or pathological

conditions that could reasonably be detected by a health care professional with appropriate training and expertise are not encompassed within this definition. GINA §§ 101(7), 102(d)(4)(17), 103(d)(8), 104(3)(C), 201(7).

[3] Genetic information also includes the embryos of a pregnant individual or family member or in the case of an individual or family member using assisted reproductive technology, any embryo that is “legally held.” Genetic information does not include gender or age. GINA §§ 101(c), 102(a)(3), 103(c), 104(b)(2), 209(b).

[4] GINA, §§ 101(d)(5)(B), 102(a)(4)(15)(B), 103(d)(6)(B), 104(b)(3)(A), 201(3)(b).

[5] H.R. Rep. No. 110-28, pt. 1 (March 5, 2007).

[6] These states include Arizona, Arkansas, California, Connecticut, Delaware, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Rhode Island, South Dakota, Texas, Utah, Vermont, Virginia, Washington and Wisconsin. See National Conference of State Legislatures, State Genetics Employment Laws, at <http://www.ncsl.org/programs/health/genetics/ndiscrim.htm> (last updated Jan. 2008).

[7] GINA, § 209(a)(1).

[8] For “employment agency” and “labor organization,” GINA refers to the definitions found in Title VII of the Civil Rights Act of 1964. “[E]mployment agency” means any person regularly undertaking with or without compensation to procure employees for an employer or to procure for employees opportunities to work for an employer and includes an agent of such a person.” “Labor organization” is “a labor organization engaged in an industry affecting commerce, and any agent of such an organization, and includes any organization of any kind, any agency, or employee representation committee, group, association, or plan so engaged in which employees participate and which exists for the purpose, in whole or in part, of dealing with employers concerning grievances, labor disputes, wages, rates of pay, hours, or other terms or conditions of employment, and any conference, general committee, joint or system board, or joint council so engaged which is subordinate to a national or international labor organization.” Civil Rights Act of 1964 § 701(c)-(d); 42 U.S.C. § 2000e.

[9] Training programs are defined as “any employer, labor organization, or joint labor-management committee controlling apprenticeship or other training or retraining, including on-the-job training programs.” GINA § 205(a).

[10] Civil Rights Act of 1964 § 703(a); 42 U.S.C. § 2000e-2.

[11] GINA §§ 202(a)(2), 203(a)(2), 204(a)(2), 205(a)(2).

[12] GINA § 207(f).

[13] GINA § 202(b).

[14] GINA §§ 202(b)(1), 203(b)(1), 204(b)(1), 205(b)(1).

[15] H.R. Rep. No. 110-28, pt. 1 (March 5, 2007).

[16] GINA §§ 202(b)(2), 203(b)(2), 204(b)(2), 205(b)(2).

[17] GINA §§ 202(b)(3), 203(b)(3), 204(b)(3), 205(b)(3).

[18] GINA §§ 202(b)(4), 203(b)(4), 204(b)(4), 205(b)(4).

[19] H.R. Rep. No. 110-28, pt. 1 (March 5, 2007).

[20] GINA §§ 202(b)(4), 203(b)(4), 204(b)(4), 205(b)(4).

[21] GINA §§ 202(b)(5), 203(b)(5), 204(b)(5), 205(b)(5).

[22] “Genetic monitoring” refers to “the periodic examination of employees to evaluate acquired modifications to their genetic material, such as chromosomal damage or evidence of increased occurrence of mutations, that may have developed in the course of employment due to exposure to toxic substances in the workplace, in order to identify, evaluate, and respond to the effects of or control adverse environmental exposures in the workplace.” GINA § 201(5).

[23] GINA §§ 202(b)(5), 203(b)(5), 204(b)(5), 205(b)(5).

[24] GINA §§ 202(c), 203(c), 204(c), 205(c).

[25] 42 U.S.C. § 12112(d)(3)(B).

[26] *Id.*

[27] Genetic information disclosed pursuant to a court order can only include the genetic information expressly authorized by the order and if the court order was secured without the individual’s knowledge, the employer, employment agency, labor organization or training program receiving the court order must inform the individual of the order and any information disclosed pursuant to the order.

[28] GINA § 206(c).

[29] GINA § 210.

[30] Disparate impact refers to an employer practice which has a disproportionate impact on a certain group even though the practice may appear to be neutral on its face and the employer may not intend to discriminate.

[31] ERISA § 702; Code § 9802.

[32] ERISA § 701(a); Code § 9801(a); Labor Reg. § 2590.701-3(b)(6); Treas. Reg. § 54.9801-3(b)(6). In the absence of a current diagnosis of illness or disease, genetic information does not constitute a preexisting condition. ERISA § 701(b)(1)(B); Code § 9801(b)(1)(B); Labor Reg. § 2590.701-3(b)(6)(ii); Treas. Reg. § 54.9801-3(b)(6)(ii).

[33] 42 U.S.C. § 300gg; HHS Reg. § 146.111(b)(6).

[34] ERISA § 702(e); Code § 9802(e); 42 U.S.C. § 300gg-1(b). Section 102(b) of the Act imposes substantially similar requirements on health insurers issuing policies in the individual marketplace. PHSA § 2753.

[35] “MediGap” policies supplement the health coverage available under the Medicare program. Section 104 of the Act amends Section 1882 of the Social Security Act (42 U.S.C. § 1395ss) to preclude discrimination in pricing or coverage by issuers of MediGap policies on the basis of genetic information, required genetic testing or requests for genetic information from covered individuals (or applicants for coverage) and their family members, or collection of genetic information. GINA §§ 104(a) & (b). The SSA amendments adopted by GINA use defined terms that are identical to those applicable to the amendments to ERISA, the Code, and PHSA. GINA § 104(b)(3). Notably, the SSA amendments do not replicate the enforcement and penalty provisions applicable under ERISA, the Code and PHSA. If the National Association of Insurance Commissioners (“NAIC”) modifies its model Section 1882 regulations prior to June 30, 2008 to conform to the SSA amendments, those model regulations will be given effect for interpretive purposes. If the NAIC does not adopt modified model regulations the prescribed deadline, the Secretary for Health and Human Services is directed to promulgate final regulations relating to the SSA amendments no later than October 1, 2008.

[36] ERISA § 702(b)(3)(A); Code § 9802(b)(3)(A); 42 U.S.C. § 300gg-1(b)(3). This limitation does not prevent a group health plan or health insurer from increasing premiums or contributions in response to a manifest disease or illness, but it does not permit increased premiums or contributions for a covered individual’s family members nor does it allow an insurer to increase the employer’s group premium. ERISA § 702 (b)(3)(B); Code § 9802(b)(3)(A); 42 U.S.C. § 300gg-1(b)(3)(B). This is consistent with the approach in effect prior to the adoption of the Act under HIPAA: group health plans and health insurers were permitted to adjust the costs of coverage and the amounts of contributions based on actual illness and disease but could not use mere health risk factors or likelihood of the development of illness or disease to discriminate against individual participants or their dependents. See note 34, above.

[37] ERISA § 702(c)(1); Code § 9802(c); 42 U.S.C. § 300gg-1(c).

[38] ERISA § 702(d); Code § 9802(d); 42 U.S.C. § 300gg-1(d). The incidental acquisition of genetic information by a group health plan or health insurer is not a violation, provided the information is not used for underwriting purposes. ERISA § 702(d)(3); Code § 9802(d)(3); 42 U.S.C. § 300gg-1(d)(3). The “incidental acquisition” exception for employers discussed above will be relevant in the context of incidental acquisitions of genetic information by group health plans because employers (or their agents) are typically responsible for administering these plans, and in most cases, the plans themselves are unlikely to independently acquire any genetic information.

[39] ERISA § 733(d)(9); Code § 9832(d)(10); 42 U.S.C. § 300gg-91(d)(19).

[40] ERISA § 702(c)(3); Code § 9802(c)(3)(A); 42 U.S.C. § 300gg-1(c)(3)(A). Under the privacy regulations adopted under HIPAA (45 C.F.R. Parts 160 and 164), “payment functions” include activities undertaken by a group health plan or health insurer to obtain premium payments or provide benefits or to secure reimbursement for the provision of health care 45 C.F.R. 164.501. The Act clarifies that a group health plan or health insurer may only request the minimum amount of genetic information necessary to complete the payment function at issue. ERISA § 702(c)(3)(B); Code § 9802(c)(3)(B); 42 U.S.C. § 300gg-1(c)(3)(B).

[41] ERISA § 702(c)(2); Code § 9802(c)(2); 42 U.S.C. § 300gg-1(c)(2).

[42] ERISA § 702(c)(4); Code § 9802(c)(4); 42 U.S.C. § 300gg-1(c)(4).

[43] ERISA § 733(d)(5); Code § 9832(d)(6); 42 U.S.C. § 300gg-91(d)(15).

[44] ERISA § 702(f); Code § 9802(f); 42 U.S.C. § 300gg-1(f).

[45] ERISA § 502(c)(9)(A); Code § 9834; 42 U.S.C. § 300gg-22(b)(3). Excise taxes imposed under the Code are based on preexisting group health plan requirements set forth in Code § 4980D.

[46] ERISA § 502(c)(9)(B); Code § 4980D(b)(1); 42 U.S.C. § 300gg-22(b)(3)(B).

[47] ERISA § 502(c)(9)(C); Code § 4980D(b)(2) & (3); 42 U.S.C. § 300gg-22(b)(3)(C).

[48] ERISA § 502(c)(9)(D)(i) & (ii); Code § 4980D(c)(1) & (2); 42 U.S.C. § 300gg-22(b)(3)(D)(i) & (ii).

[49] ERISA § 502(c)(9)(D)(iii); Code § 4980D(c)(3); 42 U.S.C. § 300gg-22(b)(3)(D)(iii).

[50] ERISA § 502(c)(9)(E); Code § 4980D(c)(4); 42 U.S.C. § 300gg-22(b)(3)(E).

[51] 42 U.S.C. § 300gg-61(b). In general, the PHSA remedial provisions defer to state insurance regulators regarding the imposition of penalties for failure to comply with the applicable requirements. 42 U.S.C. § 300gg-61(a). However, the Secretary of Health and Human Services is authorized to assess penalties of up to \$100 per day for each individual affected by a violation. 42 U.S.C. §§ 300gg-61(b)(2) & -22(b)(2).

[52] GINA §§ 101(f)(2), 102(d), 103(f) (for group health plans and health insurers, ERISA, Code, and PHSA amendments effective as of first plan year commencing after the first anniversary of enactment; for individual health insurance policies, amendments effective for policies offered, sold, issued, or renewed after the first anniversary of enactment). Group health plans operating on a fiscal year basis may be required to comply prior to January 1, 2010.

[53] GINA § 302(a).

[54] *Id.*

