In the words of John F. Kennedy, “Change is the law of life. And those who look only to the past or present are certain to miss the future.” Change has certainly been the “law of life” for group health plans in the past few years, with Congress passing several acts that require significant changes in plan administration. This legislation includes the Genetic Information Nondiscrimination Act, the Health Information Technology for Economic and Clinical Health Act, Michelle’s Law, and the Mental Health Parity and Addiction Equity Act, just to name a few. Although the effective dates vary, calendar year plans became subject to most of the new provisions as of Jan. 1, 2010.

Genetic Information Nondiscrimination Act

On May 21, 2008, President George W. Bush signed the Genetic Information Nondiscrimination Act (GINA) of 2008 into law.1 GINA prohibits group health plans, health insurers, and employers from discriminating against individuals on the basis of genetic information.2 The rules governing health plans (including ERISA and non-ERISA plans) and health insurers apply as of the first day of plan years beginning after May 21, 2009.

Prior to the enactment of GINA, health plans and health insurers were prohibited under the Health Insurance Portability and Accountability Act (HIPAA) from establishing eligibility requirements or charging higher premiums for individuals based on certain health factors. However, the adjustment of group premiums was permissible under HIPAA. GINA expands the nondiscrimination provisions to prohibit plans and insurers from setting group premium rates on the basis of genetic information. Under GINA, health insurers and health plans are prohibited from requesting or requiring genetic information of individuals or their family members and from using this information for decisions regarding coverage, rates, or pre-existing conditions. Specifically, health plans and health insurers may not do the following:

- adjust premium or contribution amounts on the basis of
Under GINA, genetic information includes an individual’s genetic tests, the genetic tests of family members (dependents and relatives up to the fourth degree), and the manifestation of a disease or a disorder in family members. The manifestation of a disease or a disorder in an individual is not considered genetic information. Thus, a plan is permitted to use the individual’s record of insurance claims to determine his or her eligibility or premium rates. By contrast, the information may not be used when determining the premiums for the individual’s family members. For example, if an employee who enrolls in a group health plan has been diagnosed with diabetes, the plan may adjust premiums for the employee’s coverage but may not consider the diagnosis when establishing the premiums for the employee’s family members. The employee’s diabetes is genetic information as it relates to his or her family members.

Underwriting and Wellness Programs

The prohibitions included in GINA have broad applications and raise questions about the permissibility of certain plan practices, particularly the structure of wellness programs. Many plans have implemented wellness programs that offer a premium discount in exchange for the employee’s completion of a health risk assessment. In some cases, the assessment seeks information about the medical history of the employee’s family, which is considered genetic information under GINA. The interim final regulations, which were published Oct. 7, 2009, define “underwriting” broadly to include rules for eligibility for benefits and computation of the amounts of premiums or contributions. The regulations explain that underwriting includes providing discounts, rebates, or other benefits in return for activities, such as completing a health risk assessment or participating in a wellness program. These rules prohibit wellness programs that provide a discount for completing a health risk assessment that collects family medical history. However, plan sponsors are permitted to offer a discount in exchange for completing a health risk assessment that does not collect family medical history. Plan sponsors who choose these types of programs must ensure that the health risk assessment clearly indicates that an employee should not disclose genetic information. The regulations permit plan sponsors to request that employees complete health risk assessments that collect genetic information, provided no reward is offered and the information is not obtained prior to or in connection with enrollment in a wellness program.

A Few Exceptions

GINA contains some notable exceptions. The act does not apply to life insurance, disability insurance, or long-term care insurance. In addition, GINA does not mandate coverage for a particular test or treatment. Health insurers and health plans are not prohibited from obtaining and using genetic test results in making health insurance payment determinations. However, any request for information must be limited to the minimum amount necessary to make such a determination. Finally, obtaining genetic information that is incidental to the collection of other information does not violate the act, provided the information has not been collected for underwriting purposes (for example, a plan participant completes a health risk assessment that requests information about family medical history after becoming enrolled in the plan, and no premium or reward is offered for completing the assessment).

Provisions to Protect Privacy

GINA amends the privacy standards under HIPAA to expand the definition of protected health information (PHI) to include genetic information. In addition, health plans may not use or disclose PHI that is genetic information for underwriting purposes, even if the individual has signed an authorization for the plan to do so.

Health Information Technology for Economic and Clinical Health Act

On Feb. 17, 2009, President Barack Obama signed the American Recovery and Reinvestment Act of 2009, which included the Health Information Technology for Economic And Clinical Health (HITECH) Act. Some significant changes related to HIPAA compliance affect both covered entities and business associates. The general provisions of this act take effect on Feb. 17, 2010, except as otherwise provided. Among other things, the act extends certain privacy and security obligations to business associates directly, imposes a new notification requirement upon breach of unsecured PHI, and enhances enforcement provisions.

Increased Obligations for Business Associates

Historically, the privacy and security requirements were directly applicable to covered entities—including health plans, health care clearinghouses, and certain health care providers. Business associates or third parties—such as plan administrators, attorneys, and accountants—who provide services to covered entities and receive PHI pursuant to the performance of those services, were subject to certain restrictions but only under the terms of the agreements entered into with covered entities.

Under the HITECH Act, many of the security and privacy standards included in HIPAA are now applicable to business associates in the same manner as the standards are applied to covered entities. Business associates must implement administrative, technical, and physical safeguards to protect the confidentiality and integrity of PHI and electronic PHI (e-PHI). For example, business associates must implement policies to detect security violations and designate a security official, who is responsible for overseeing compliance with the security standards. Business associates must also establish safeguards for workstations that access PHI and e-PHI and also ensure authentication of the identities of individuals or entities that may have access to protected information. Business associates must also train their employees on HIPAA’s requirements.
With regard to privacy, business associates may not use or disclose PHI, except as permitted by the regulations. (Generally, a covered entity may use or disclose PHI for purposes of treatment, payment, or health care operations; otherwise, an authorization is required.) When using or disclosing PHI, business associates must make reasonable efforts to limit disclosure to the minimum necessary to accomplish the intended purpose.

**Notice of Breach of Unsecured Protected Health Information**

As a key change under this act, covered entities and business associates are subject to new notification requirements in the case of a breach of unsecured PHI. The Department of Health and Human Services (DHHS) issued interim final rules implementing the notification requirement, which became effective Sept. 23, 2009. However, the DHHS will not impose sanctions for failure to provide notice of breaches that are discovered before Feb. 22, 2010. According to the rules, a breach does not occur unless the unauthorized use or disclosure of PHI violates the HIPAA privacy standards.

**Important Definitions**

The notice requirements apply only to a breach of unsecured PHI, which is PHI that has not been secured through the use of technology or methodology specified by the DHHS. Under a safe harbor rule established by the department, encryption and destruction are the only two ways to secure PHI and avoid the rules that require notification of a breach.

The definition of “breach” is limited to a use or disclosure that “compromises the security or privacy” of PHI, which the DHHS has interpreted as information that “poses a significant risk of financial, reputational, or other harm to the individual.” Thus, covered entities and business associates must perform a risk assessment when determining whether a breach has occurred. For example, if information is improperly disclosed but includes only the name of an individual and the fact that he or she has been treated at a hospital, the disclosure may constitute a violation of the privacy standards but is not likely to be regarded as a breach under the act. By contrast, the improper disclosure of a list of individuals who received treatment at a substance abuse facility is probably considered a breach.

**Notice Requirements**

Covered entities that experience a breach must notify the affected individual as well as the DHHS. If the breach involves more than 500 people, the DHHS must be notified immediately, and the department must post a list of covered entities that experience a breach of this magnitude on its Web site. Furthermore, if the breach involves information about more than 500 individuals in a particular state or jurisdiction, the covered entity must notify “prominent media outlets” (for example, newspapers and broadcast media) in the area. If the breach involves fewer than 500 people, covered entities may keep a log of such breaches and submit it to the DHHS annually (60 days after the end of the calendar year). Business associates that discover a breach of unsecured PHI must notify entities covered under the plan. Unless immediate notice is required, notice must be given without unreasonable delay and in no case later than 60 days after a breach has been discovered.

Any notice provided under this rule must be written in plain language and sent via first-class mail or e-mail, provided the individual previously consented to receive electronic notice. Among other things, the notice must include the following:

- a brief description of what happened, including the date of the breach and date of discovery, if known;
- a description of the unsecured PHI involved in the breach (such as the individual's full name, Social Security number, date of birth, home address, and so forth);
- any steps the individual should take to protect himself or herself from potential harm resulting from the breach;
- a description of the covered entity's efforts to investigate the breach, mitigate any resulting harm, and protect against further breaches; and
- contact information to enable individuals to ask questions or learn additional information (for example, toll-free telephone number, e-mail address, Web site, and so forth).

**Exceptions**

The notice requirements do not apply if an employee of a covered entity or business associate unintentionally acquires, accesses, or uses PHI in good faith in that employee's normal scope of professional responsibilities. In addition, inadvertent disclosure by one person who has authorized access to another person who also has authorized access does not require notification. Finally, unauthorized disclosures in which an unauthorized person to whom PHI is disclosed would not reasonably have been able to retain the information do not require notification (for example, if a health plan mails an “Explanation of Benefits” to the wrong individual, but the form is returned to the post office as undeliverable).

**Heightened Enforcement and Penalties**

The HITECH Act imposes greater penalties for violations of HIPAA's privacy and security standards. Those penalties are now applicable to both covered entities and business associates. Notably, these changes took effect immediately upon enactment. The amount of civil penalties—which ranges from $100 to $50,000 per violation (up to a maximum penalty of $1.5 million)—depends on whether the entity had knowledge of the breach, whether the violation was attributable to reasonable cause or the result of willful neglect, and whether the violation has been corrected. Criminal penalties of fines, imprisonment for up to 10 years, or both may be imposed if persons knowingly violate HIPAA (that is, if they have knowledge of the facts that constitute the offense). The act requires the DHHS to ensure compliance by conducting periodic audits of covered entities and business associates. This provision is a significant development: Under prior law, audits were con-
ducted only if the DHHS Office of Civil Rights received a complaint alleging that a covered entity had violated the law's privacy or security standards.

**Michelle’s Law**

Michelle Morse was a normal college student at Plymouth State University until she was diagnosed with colon cancer. Because of the toll chemotherapy would take on her body, Michelle’s doctors advised her that she should reduce her course load. At this point, Michelle’s mother, Ann Marie, faced the ironic reality that following the doctor’s orders would result in losing health insurance coverage for Michelle and paying monthly COBRA premiums that the family could not afford. Consequently, Michelle maintained her course load in an effort to retain her health insurance coverage. Michelle died of colon cancer in 2005 at the age of 22. Michelle’s mother lobbied the New Hampshire state legislature, and New Hampshire was the first state to pass “Michelle’s Law” in 2006. The federal version of this law was signed by President Bush on Oct. 9, 2008, and the law is effective for plan years beginning on or after Oct. 9, 2009.10

Under current law, many group health plans conditioned eligibility for coverage of dependents who are between the ages of 19 and 23 on their status as full-time students. However, Michelle’s Law mandates a change for dependent students who are seriously ill. Michelle’s Law prohibits group health plans from terminating coverage of dependent children because of a “medically necessary” leave of absence from—or change in enrollment at—a college or university that commences while the child is suffering from a “serious illness or injury.” The law applies to ERISA plans as well as to church and governmental plans. (Self-funded nonfederal governmental plans may opt out of the act’s requirements by issuing a notice of opt-out to enrollees at the time of enrollment and on an annual basis. The notice must be filed with the Centers for Medicare and Medicaid Services.)

To qualify for continued coverage, a dependent child must have been enrolled at a postsecondary institution immediately before the first day that he or she needed to take a medically necessary leave of absence. In addition, the dependent child must have written certification from a physician, stating that the child is suffering from a serious illness or injury and the leave is medically necessary. The plan must continue covering the child until the earlier of one year after the first day of the leave or the date on which the coverage would otherwise terminate under the terms of the plan (for example, when a dependent reaches the plan’s limiting age).

**Mental Health Parity and Addiction Equity Act**

On Oct. 3, 2008, President Bush signed the Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008.11 This bill amends the Mental Health Parity Act of 1996, which required group health plans with annual dollar limits or aggregate lifetime dollar limits for medical and surgical benefits to apply the same limits to mental health benefits. The MHPAEA expands the Mental Health Parity Act to apply to benefits for treatment for substance abuse and requires equality in financial requirements and treatment limitations for benefits for treating mental health and substance abuse. These changes are effective for plan years beginning after Oct. 3, 2009.

The MHPAEA does not require group health plans to offer benefits for treatment of mental health or substance use disorders. Only plans that offer physical, medical, and surgical benefits, together with benefits for either mental health or substance use disorders are affected by the MHPAEA. Key changes under the act include the following:

- A group health plan cannot impose more restrictive annual or lifetime limits on mental health or substance use disorder benefits than those imposed on medical and surgical benefits.
- Mental health benefits and substance use disorder benefits may not be subject to any separate cost-sharing requirements that are only applicable to such benefits.
- If a group health plan includes medical and surgical benefits and either mental health or substance use disorder benefits, the plan cannot impose more restrictive financial requirements or treatment limitations on the mental health or substance use disorder benefits than the most common financial requirements imposed on medical and surgical benefits. These financial requirements include items such as deductibles, co-payments, co-insurance and out-of-pocket expenses. Examples of treatment limitations include the number of visits or days of coverage.
- If a group health plan includes medical and surgical benefits and mental health and/or substance use disorder benefits and also provides out-of-network medical and surgical benefits, the plan must provide out-of-network mental health and/or substance use disorder benefits.
- Standards for determining medical necessity and reasons for any denial of benefits relating to mental health benefits and substance use disorder benefits must be made available to plan participants upon request.

The MHPAEA applies to group health plans subject to ERISA, nonfederal governmental plans, and church plans. (Self-funded nonfederal governmental plans may opt out in accordance with the Centers for Medicare and Medicaid Services rules.) Small businesses or those with 50 or fewer employees during the previous calendar year are exempt from the parity requirements. In addition, the act contains a cost exemption. If a group health plan experiences an increase in cost exceeding 2 percent of the plan’s costs for the first year or 1 percent in subsequent years, a plan may not be required to comply with the new requirements for one year. To qualify for this cost exemption, a plan must comply with the parity requirements for at least six months before claiming the exemption.

Additional guidance on compliance with the MHPAEA is anticipated. Regulations should be issued in January 2010, and the Departments of Health and Human Services, Treasury, and Labor have indicated that their goal is to make

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it easier for health plans and insurers to implement the provisions of this act.

**Impact of the New Laws on Employers**

GINA, the HITECH Act, Michelle’s Law, and the Mental Health Parity and Addiction Equity Act made significant changes to the laws governing group health plans. Employers who sponsor group health plans must review their plans and governing policies and procedures and implement the necessary changes to ensure compliance. TFL

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**Endnotes**


2GINA contains two titles. Title I governs health plans and insurers. Title II applies to employers with at least 15 employees and prohibits discrimination with respect to compensation, terms, conditions, or privileges of employment. Employers became subject to the provisions of Title II on Nov. 21, 2009.

3A genetic test is any analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. Tests to evaluate cholesterol levels, blood count, liver function, or blood alcohol levels are not genetic tests. However, a test to determine whether an individual has a genetic variant associated with a medical condition is a genetic test. 26 C.F.R. § 54.9802-3T(a)(5)(i).


5The EEOC issued informal letters warning employers that disability-related questions contained in health risk assessments may violate the Americans with Disabilities Act. See EEOC Informal Letters, Jan. 6, 2009, and March 6, 2009.


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8With regard to “material change,” see Teamsters Local No. 287, 304 NLRB at 120; Teamsters, 255 NLRB 1091, 1092 (1981); and Hot Shoppes Inc., 143 NLRB 578, 581 (1965).


11Supra note 31.

1245 U.S.C. 151. Note that the RLA explicitly exempts from its regulatory ambit even those “trucking services” performed by a company commonly owned and operated with an RLA carrier. Thus, the “express carrier” provision is absolutely essential to FedEx Express if its growing trucking operations threaten previous NMB rulings.

1349 U.S.C. 10501 et seq.


15109 Stat. 803, 950 (1995); see also David Barnes, Express Carrier Battle Heats Up on Capitol Hill, TRAFFIC WORLD (July 29, 1996).


43Oberstar amendment to H.R. 2881, amending § 201 of the RLA.


45If the union does not receive 50 percent of the votes plus one systemwide, it is not certified. That is what seemed so enticing to UPS in 1995. Had the NLRB permitted UPS ground-service employees to be covered by the RLA and had a new vote for representation been engineered, UPS could have ousted the Teamsters Union as representatives of its ground-service employees if the Teamsters had not been able to meet the threshold established for the vote.