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# **The Genetic Information Nondiscrimination Act of 2008 and the Patient Protection and Affordable Care Act of 2010: Overview and Legal Analysis of Potential Interactions**

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May 1, 2015

**Congressional Research Service**

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[www.crs.gov](http://www.crs.gov)

R41314

## Summary

Upon the enactment of the Patient Protection and Affordable Care Act (ACA), as amended, certain questions have been raised about how the ACA might affect existing law. One such existing law, the Genetic Information Nondiscrimination Act (GINA), is a civil rights statute and has as its purpose the prohibition of discrimination against individuals on the basis of genetic information. In order to effectuate this prohibition, GINA not only contains certain requirements for health insurance and a general prohibition of employment discrimination provisions, but also has strong privacy protections. On the other hand, the ACA is comprehensive health care legislation that is intended to, among other things, enhance consumer protections in the private health insurance market. Both GINA and the ACA contain provisions affecting certain elements of health insurance, as well as employment-based wellness programs. The ACA, the more recent statute, does not specifically amend GINA and also does not reference GINA's requirements. The two laws serve different but complementary purposes, and there is no explicit conflict or contradiction in their terms. Still, the interaction of these two acts may be analyzed.

This report provides a brief overview of GINA; an overview of relevant ACA and GINA provisions relating to the provision of health insurance through the private market and the implementation of employer wellness programs; and statutory analysis of the potential interactions between the related provisions in both laws.

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## Background

With the passage of the health reform law, interest turned to determining not only how the new law may be interpreted and implemented, but also how it may interact with existing law. The Patient Protection and Affordable Care Act of 2010 (ACA, P.L. 111-148, as amended by the Health Care and Education Reconciliation Act, P.L. 111-152), among other things, created a number of significant reforms to the private health insurance market. These reforms include changes that will limit the ability of a group health plan or health insurance issuer to set premiums or determine eligibility for coverage based on criteria such as health status. Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA, P.L. 110-233) also contains requirements affecting health insurance premiums and coverage eligibility, and thus questions may be raised about the potential for interaction between these two acts.

In addition, the ACA includes provisions relating to the implementation of employer wellness programs. Title II of GINA prohibits discrimination in employment based on genetic information and generally prohibits the collection of genetic information. However, there is a specific exception for wellness programs with attendant privacy protections. This raises questions about the potential for interaction between these two sets of provisions, specifically with respect to requirements around the release of genetic information and incentives for participation in such a program.

This report provides a brief overview of GINA, an overview of relevant ACA and GINA provisions relating to the provision of health insurance through the private market, an overview of relevant ACA and GINA provisions relating to the implementation of employer wellness programs, and statutory analysis of the potential interactions between the related provisions in both laws.<sup>1</sup>

## GINA Overview

On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA), referred to by its sponsors as the first civil rights act of the 21<sup>st</sup> century, was enacted. GINA prohibits discrimination by health insurers and employers based on genetic information. Genetic information is considered sensitive for a number of reasons, including that it may be predictive or indicate a predisposition to disease, and that it can affect not only an individual but also family members.<sup>2</sup>

GINA is divided into two main parts: Title I, which prohibits discrimination in health insurance based on genetic information, and Title II, which prohibits discrimination in employment based on genetic information. Title I of GINA amends the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHSA), and the Internal Revenue Code (IRC),<sup>3</sup> as

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<sup>1</sup> The ACA includes provisions for the grandfathering of health insurance plans in existence on the date of enactment of the act (i.e., March 23, 2010). Grandfathered plans are exempt from the majority of new insurance reforms created by the ACA. It should be noted that some of the issues addressed in this report may not apply to grandfathered plans. For more information on grandfathered plans, see CRS Report R41166, *Grandfathered Health Plans Under the Patient Protection and Affordable Care Act (ACA)*, by (name redacted).

<sup>2</sup> For more information about GINA, see CRS Report RL34584, *The Genetic Information Nondiscrimination Act of 2008 (GINA)*, by (name redacted) and (name redacted).

<sup>3</sup> In general, Title XVII of the PHSA, along with parallel provisions in Part 7 of ERISA and Subchapter B of chapter (continued...)

well as the Social Security Act (SSA), to prohibit group health plans<sup>4</sup> and health insurance issuers<sup>5</sup> providing group and individual health coverage from engaging in genetic discrimination and to strengthen and clarify existing HIPAA nondiscrimination and portability provisions with respect to genetic information and genetic testing.<sup>6</sup> The complexity of the health care financing system required this multifaceted approach in order to ensure protection for all individuals, regardless of their coverage arrangements.<sup>7</sup> On October 7, 2009, the Departments of Labor, Health and Human Services, and Treasury issued interim final regulations implementing the majority of provisions in Title I of GINA. These regulations became effective as of December 7, 2009, and specifically for plan years beginning on or after December 7, 2009, for group health plans and health insurance issuers.<sup>8</sup> In addition, on January 25, 2013, the Department of Health and Human Services, Office for Civil Rights, published a final rule to implement Section 105 of GINA.<sup>9</sup>

Title II of GINA prohibits discrimination in employment based on genetic information and, with certain exceptions, prohibits an employer from requesting, requiring, or purchasing genetic information. The law prohibits the use of genetic information in employment decisions—including hiring, firing, job assignments, and promotions—by employers, unions, employment agencies, and labor management training programs. On November 9, 2010, the Equal

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(...continued)

100 of the IRC, govern the nature and content of health insurance coverage provided primarily in the private sector. Prior to the ACA, many of the provisions dealing with the regulation of private health insurance in these three laws were added by the Health Insurance Portability and Accountability Act (HIPAA), which was designed to improve health care access, portability, and renewability. P.L. 104-191, 110 Stat. 1936 (1996). The ACA also amends these three laws to create new requirements for private health coverage.

<sup>4</sup> “Group health plans” may be defined as employee benefit plans (i.e., plans established by an employer or an employer organization) that provide medical care to employees or their dependents directly or through insurance, reimbursement, or otherwise. *See, e.g.*, 42 U.S.C. §300gg-91(a)(1). A group health plan may include a self-insured plan, which is a plan that is provided by the organization seeking health coverage for its members. Such organizations pay for health benefits directly, as the organization itself bears the risk for covering medical expenses (as opposed to an insurer).

<sup>5</sup> A “health insurance issuer” is an insurance company, insurance service, or insurance organization that is licensed to engage in the business of insurance in a state and that is subject to state law that regulates insurance. 42 U.S.C. §300gg-91(b)(2).

<sup>6</sup> HIPAA established certain nondiscrimination requirements that are intended to prevent group health plans and health insurance issuers from discriminating against individual participants or beneficiaries based on a “health status-related factor.” In particular, HIPAA amended the PHS, ERISA, and the IRC to prohibit group health plans and health insurance issuers from basing coverage eligibility rules on these health status factors, which include health status (physical or mental), claims experience, receipt of health care, medical history, evidence of insurability, or disability, and genetic information. *See, e.g.*, 29 U.S.C. §1182. In addition, group health plans and health insurance issuers may not require that an individual pay a higher premium or contribution than another “similarly situated” participant based on these factors. The ACA retains these requirements and extends them to health insurance issuers in the individual market.

<sup>7</sup> In general, the PHS, ERISA, and the IRC govern different types of health plans and health insurance coverage. For example, the PHS covers some self-insured group health plans (non-federal governmental plans), as well as health insurance issuers providing group health coverage and coverage in the individual market. *See* 42 U.S.C. §300gg-21. ERISA covers group health plans (including private-sector self-insured plans) and health insurance issuers providing group health coverage, and it does not cover governmental plans, church plans, or insurance in the individual market. *See* 29 U.S.C. §1003. The IRC covers group health plans, including church plans, but does not cover health insurers.

<sup>8</sup> 74 *Federal Register* 51633 (October 7, 2009).

<sup>9</sup> 78 *Federal Register* 5566 (January 25, 2013).

Employment Opportunity Commission (EEOC) issued final regulations for Title II that take effect on January 10, 2010. These regulations generally closely track the statutory language.<sup>10</sup>

## **GINA Title I and the ACA**

### **Introduction**

GINA prohibits the use of genetic information in determining premiums for individuals or groups or for serving as the basis for conditioning health coverage. The ACA, on the other hand, specifically defines the factors on which insurers may predicate issuance of coverage or determination of premiums. Thus, questions may be raised as to how the two statutes might interact with one another in the specific area of private health insurance market reforms. This section provides an overview of relevant GINA and ACA provisions concerning coverage eligibility and premium determination to provide context for a statutory analysis outlining the potential interactions between the relevant provisions.

### **GINA**

Broadly, GINA prohibits group health plans and health insurance issuers from engaging in three practices: (1) using genetic information about an individual to adjust a group plan's premiums, or, in the case of individual plans, to deny coverage, adjust premiums, or impose a preexisting condition exclusion;<sup>11</sup> (2) requesting, requiring, or purchasing genetic information for underwriting purposes or prior to enrollment; and (3) requiring or requesting genetic testing. Each of these prohibitions is discussed below in more detail.

#### ***Premium Determination***

GINA prohibits health plans, group and individual health insurance issuers, and issuers of Medicare supplemental policies from adjusting a group or individual's premium or contribution amount based on genetic information about an individual in the group, an individual seeking individual coverage, or an individual's family members.<sup>12</sup>

#### ***Collection and Use of Genetic Information Restricted***

GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from requesting, requiring, or purchasing genetic information for the purposes of underwriting or prior to an individual's enrollment or in connection with

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<sup>10</sup> 75 *Federal Register* 68912 (November 9, 2010). For a general discussion of the regulations see CRS Report R41527, *The Genetic Information Nondiscrimination Act (GINA): Final Employment Regulations*.

<sup>11</sup> For purposes of the GINA and ACA requirements, a "preexisting condition exclusion" means a limitation or exclusion of benefits relating to a condition that was present before the date of enrollment for health coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date. 42 U.S.C. §300gg-3(b)(1)(A). Excluding coverage for preexisting conditions refers to the case in which an applicant for coverage is offered a health insurance policy but that policy does not provide benefits for certain medical conditions.

<sup>12</sup> See, e.g., P.L. 110-233, §101(a). 29 U.S.C. §1182(b)(3).

enrollment.<sup>13</sup> “Incidental collection” of genetic information—genetic information obtained incidentally to the requesting, requiring, or purchasing of other information concerning any individual—would not be considered a violation of the prohibition on collecting genetic information prior to enrollment if it is not done for underwriting purposes. “Underwriting purposes,” as defined by GINA, includes (1) rules for, or determination of, eligibility for benefits; (2) the computation of premium or contribution amounts; (3) the application of any preexisting condition exclusion; and (4) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.<sup>14</sup>

GINA also prohibits individual insurers from conditioning eligibility or continuing eligibility on genetic information, and prohibits individual insurers from treating genetic information as a preexisting condition. Issuers of supplemental Medicare policies may not deny or condition the issuance of a policy based on genetic information (and may not impose a preexisting condition exclusion based on genetic information).<sup>15</sup>

### ***Genetic Testing Requirements Prohibited***

GINA prohibits health plans, group and individual health insurance issuers, and issuers of Medicare supplemental policies from requesting or requiring that individuals or their family members undergo a genetic test.<sup>16</sup> This prohibition does not limit the authority of a health care professional to request that an individual undergo genetic testing as part of his or her course of health care. The act provides for a research exception to this provision, by allowing a group or individual insurance issuer to request, but not require, an individual to undergo genetic testing if specific conditions are met.<sup>17</sup>

## **The ACA**

As noted above, the ACA creates new federal standards applicable to private health insurance coverage. The ACA establishes new rating requirements that allow insurers to vary premiums based only on certain key characteristics.<sup>18</sup> These characteristics are self or family enrollment in a plan or coverage; rating area (as established by a state and reviewed by the Secretary); age (by no more than a 3:1 ratio across age rating bands established by the Secretary, in consultation with the National Association of Insurance Commissioners [NAIC]); and tobacco use (by no more than a 1.5:1 ratio). Thus, health insurance issuers subject to this provision are precluded from charging premiums based on health factors and other additional criteria (e.g., the sex of the covered individual). Further, the ACA prohibits group health plans and health insurance issuers in the individual and group markets from excluding coverage for preexisting health conditions.<sup>19</sup> In addition, the ACA requires individual and group health insurance issuers to offer coverage on a guaranteed issue and guaranteed renewal basis.<sup>20</sup> Under the act, health insurance issuers offering

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<sup>13</sup> See, e.g., P.L. 110-233, §101(b). 29 U.S.C. §1182(d).

<sup>14</sup> See, e.g., P.L. 110-233, §101(d). 29 U.S.C. §1191b.

<sup>15</sup> P.L. 110-233, §104(a). 42 U.S.C. 1395ss(s)(2).

<sup>16</sup> See, e.g., P.L. 110-233, §101(b). 29 U.S.C. §1182(c)(1).

<sup>17</sup> See, e.g., P.L. 110-233, §101(b). 29 U.S.C. §1182(c)(4).

<sup>18</sup> P.L. 111-148, §1201 (§2701 of the PHSA).

<sup>19</sup> P.L. 111-148, §1201 (§2704 of the PHSA).

<sup>20</sup> P.L. 111-148, §1201 (§2702 of the PHSA).

health insurance coverage in the individual or group market in a state must accept every employer and individual in the state that applies for such coverage, subject to certain conditions. Further, the ACA provides that health insurance issuers offering coverage in the individual or group market must renew or continue in force such coverage at the option of the plan sponsor or the individual, subject to exceptions such as nonpayment of premiums, or an act or practice of fraud.<sup>21</sup> Thus, based on these provisions, a health insurance issuer would be precluded from denying coverage, or denying a renewal of coverage, based on factors such as the individual's health.

## **Analysis of Title I of GINA and the ACA**

In examining provisions of GINA in relation to comparable provisions in Title I of the ACA pertaining to health insurance, there appears to be some overlap in the reach of these acts. For example, under GINA, a group health plan and a health insurance issuer may not adjust premium or contribution amounts on the basis of genetic information.<sup>22</sup> Alternatively, under Section 2701 of the PHSA, as created by the ACA, certain health insurance issuers may only vary premiums based on certain specified factors (i.e., tobacco use, age, geographic area, and self-only or family enrollment). In evaluating the interaction of these two statutes, one may argue that it is possible to read these statutes together as establishing non-conflicting limitations on insurance premiums. While the ACA creates criteria for premium rates, GINA prohibits premium adjustments based on genetic information. Further, it seems that a health insurance issuer can simultaneously comply with the requirements of the ACA and GINA. While a violation of this provision of GINA may also be a violation of Section 2701 of the PHSA, there does not appear to be a barrier to offering penalties for the same conduct under these two statutes. Though one may argue that Section 2701 of the PHSA renders GINA, at least in part, ineffective and therefore amends or repeals GINA by implication, given that amendments by implication are disfavored, and without a demonstrated clear intention to override its provisions,<sup>23</sup> a court may be more likely to dismiss this argument.

Further, it should be noted that these provisions of the ACA and GINA are not identical in scope. For example, the limitations on premium amounts as added by the ACA apply only to health insurance issuers in the individual and small group markets, and do not apply (as GINA does), for example, to self-insured group health plans or insurers in the large group market. Further, this section of the ACA applies only to premium rates, whereas GINA applies to premiums as well as contribution amounts.<sup>24</sup> The provisions of GINA seem likely to remain intact, because the reach of GINA is beyond that of the ACA and, where there is not a direct conflict, courts are reluctant to amend or repeal a statute by implication.

As discussed above, GINA also prohibits group health plans and health insurance issuers from requesting, requiring, or purchasing genetic information for the purposes of underwriting or prior to an individual's enrollment or in connection with enrollment. As mentioned above, underwriting purposes include, among other things, rules or determination of eligibility for benefits, the

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<sup>21</sup> P.L. 111-148, §1201 (§2704 of the PHSA).

<sup>22</sup> *See, e.g.*, P.L. 110-233. Section 202(b); 29 U.S.C. §1182(b)(3).

<sup>23</sup> *See e.g.*, *United States v. Borden Co.*, 308 U.S. 188, 198 (1939), as cited in *Watt v. Alaska*, 451 U.S. 259, 267 (1981).

<sup>24</sup> GINA and its accompanying regulations do not define contribution amounts, but it is possible that contribution amounts encompass certain cost-sharing elements of health insurance coverage, including co-payments and deductibles.



application of any preexisting condition exclusion, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits. The ACA, however, curtails application of these underwriting practices and contains requirements related to insurance enrollment. For example, under the ACA, a group health plan and a health insurance issuer will no longer be able to impose a preexisting condition exclusion.<sup>25</sup> In addition, as discussed above, health insurance issuers must accept every individual and employer that applies for coverage and renew or continue such coverage at the option of the plan sponsor or individual. Thus, it seems that the provisions of the ACA may obviate some of the requirements of GINA. If a health insurance issuer generally cannot use certain underwriting practices or limit enrollment to certain individuals, they may not be inclined to obtain genetic information for these purposes. However, this is not to say that GINA is therefore repealed by the ACA. It is likely that a court may read these statutes in concert with each other: while the ACA removes certain limitations to obtaining health insurance, GINA prohibits obtaining genetic information as part of certain insurance practices. Further, it should also be noted that these provisions of GINA and the ACA are also not identical in scope. For example, the guaranteed availability and renewability requirements of the ACA apply only to health insurance issuers and, accordingly, the effects of this provision of GINA on self-insured group health plans may not be affected by the ACA.<sup>26</sup>

Finally, in terms of the prohibition on group health plans and health insurers from requiring an individual or family member to undergo a genetic test, there does not seem to be a comparable provision in the ACA. Given no express language in the ACA that alters this provision, and because the ACA does not seem to have a requirement that interacts with this provision, it appears that this requirement is also not affected by the ACA.

## **GINA Title II and the ACA**

### **Introduction**

GINA and the ACA both include provisions that relate specifically to employer wellness programs, although neither statute specifically requires the use of wellness programs. In GINA, the relevant provisions are limited to the conditions under which an employer might lawfully collect genetic information pursuant to an employer wellness program. The ACA's provisions are broader, encourage the use of wellness programs, and include specifics about these programs, including the extent of financial incentives that an employer may use to encourage participation in wellness programs. This raises questions about the potential interaction between these two statutes with respect to employer wellness programs. This section provides an overview of relevant employer wellness program provisions in GINA and the ACA to provide context for a statutory analysis of the potential interactions between these provisions.

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<sup>25</sup> P.L. 111-148, §1201 (§2704 of the PHSA).

<sup>26</sup> It should also be noted that the provisions of the ACA discussed in this section do not apply to Medicare supplemental benefits. 42 U.S.C. §300gg-91(c)(4). Thus, these requirements of GINA are likely unaffected by the ACA.

## Employer Wellness Programs

As the cost of health insurance has continued to rise in recent years,<sup>27</sup> employers providing health insurance, as well as other insurance providers, have worked to find ways to contain costs. This has led to the introduction of incentives to promote healthy behaviors, often referred to as wellness programs. These programs take a myriad of forms, from providing a gym at the workplace to subsidizing the co-pays of certain medications and linking health care benefits or discounts to certain healthy lifestyles. In Arkansas, for example, state employees who exercise more frequently or eat healthier foods can earn up to three extra days off from work each year.<sup>28</sup> These healthy lifestyle programs can include requirements for no tobacco use, as well as requirements for certain cholesterol, blood pressure, and body mass index (BMI) measurements.<sup>29</sup>

## GINA

Most, if not all, employer wellness programs collect medical information from participants. Programs may request or require participating employees to answer questions about family history of certain diseases, conditions, or disorders. This information falls under the definition of genetic information under GINA, and therefore its acquisition and use by employers is strictly regulated and is protected differently than is employer acquisition of other medical information.<sup>30</sup>

GINA broadly prohibits both the acquisition of genetic information, as well as the use of genetic information by employers in employment decisions; however, it does provide for several exceptions to the prohibition on employer acquisition of this information. Specifically, Title II of GINA allows employers, employment agencies, labor organizations, and training programs to acquire genetic information pursuant to the offering of health or genetic services, including services offered as part of a wellness program.<sup>31</sup> The statute states, in pertinent part, “[i]t shall be an unlawful employment practice for an employer to request, require, or purchase genetic information with respect to an employee or a family member of the employee except – ... (2) where health or genetic services are offered by the employer, including such services offered as part of a wellness program.”<sup>32</sup> The exception provided for by this provision is materially identical for employment agencies, labor organizations, and training programs.<sup>33</sup>

However, employers may collect genetic information as part of a wellness program, pursuant to this exception, *only* if they meet three requirements:

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<sup>27</sup> See, for example, “2014 Employer Health Benefits Survey,” Kaiser Family Foundation, accessed at <http://ehbs.kff.org/pdf/2011/8225.pdf>.

<sup>28</sup> National Conference of State Legislatures, *State Employee Health Benefits* (Updated February 28, 2010).

<sup>29</sup> For a discussion of these types of wellness programs, see Lucinda Jesson, “Weighing the Wellness Programs: The Legal Implications of Imposing Personal Responsibility Obligations,” 15 Va. J. Soc. Policy and Law 217 (2008).

<sup>30</sup> Title II of GINA defines genetic information as “with respect to any individual, information about such individual’s genetic tests, the genetic tests of family members of such individual, and the manifestation of a disease or disorder in family members of such individual.” P.L. 110-233, Section 201(4)(A); 42 U.S.C. §2000ff(4).

<sup>31</sup> P.L. 110-233, Section 202(b)(2), Section 203(b)(2), Section 204(b)(2), and Section 205(b)(2); 42 U.S.C. §§2000ff-1(b)(2), 2000ff-2(b)(2), 2000ff-3(b)(2), and 2000ff-4(b)(2).

<sup>32</sup> P.L. 110-233, Section 202(b); 42 U.S.C. §2000ff-1(b).

<sup>33</sup> P.L. 110-233, Section 203(b)(2), Section 204(b)(2), and Section 205(b)(2); 42 U.S.C. §§2000ff-2(b)(2), 2000ff-3(b)(2), and 2000ff-4(b)(2).

- the employee must provide prior, knowing, voluntary, and written authorization;
- only the employee and the licensed health care professional or board-certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and
- any individually identifiable genetic information provided in connection with the health or genetic services provided under this exception is only available for the purposes of such services and shall not be disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees.<sup>34</sup>

The EEOC final regulations reiterate the exception for wellness programs and its requirements.<sup>35</sup> In the proposed regulations, EEOC emphasized that such programs must be voluntary, and asked for comments concerning the appropriate level of inducement offered for participation in a wellness program. In the final regulations, the EEOC concluded that inducements may be offered to encourage individuals to participate in wellness programs, but inducements may not be offered to provide genetic information. The EEOC provides the following example in the regulations as a situation that does not violate GINA:

A covered entity offers \$150 to employees who complete a health risk assessment with 100 questions, the last 20 of them concerning family medical history and other genetic information. The instructions for completing the health risk assessment make clear that the inducement will be provided to all employees who respond to the first 80 questions, whether or not the remaining 20 questions concerning family medical history and other genetic information are answered.<sup>36</sup>

However, if the health risk assessment does not make clear which questions must be answered, it would violate GINA.<sup>37</sup>

Similarly, the regulations state that financial inducements may be offered to encourage participation in wellness programs for individuals who have voluntarily provided genetic information. In order to comply with GINA, these programs must also be offered to individuals with health conditions or life style choices that put them at an increased risk of developing a condition. For example, it would not violate GINA to offer \$150 for participation in a weight loss program to employees who voluntarily disclose a family history of diabetes, heart disease, or high blood pressure, and to employees who have a current diagnosis of one of these conditions.<sup>38</sup>

Importantly, regardless of how an employer may acquire genetic information (either inadvertently or through these exceptions), the employer is still absolutely prohibited from using the information to discriminate in employment decisions, such as hiring, firing, and promotion.

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<sup>34</sup> P.L. 110-233. Section 202(b)(2)(B),(C), and (D); 42 U.S.C. §2000ff-1(b)(2)(B),(C), and (D).

<sup>35</sup> 29 C.F.R. §1635.8(b)(2), *75 Federal Register* 68935 (November 9, 2010).

<sup>36</sup> 29 C.F.R. §1635.8(b)(2)(ii)(A), *75 Federal Register* 68935 (November 9, 2010).

<sup>37</sup> 29 C.F.R. §1635.8(b)(2)(ii)(B), *75 Federal Register* 68935 (November 9, 2010).

<sup>38</sup> 29 C.F.R. §1635.8(b)(2)(iii), *75 Federal Register* 68935 (November 9, 2010).

## The ACA

The ACA contains several provisions specifically relating to wellness programs.<sup>39</sup> Of most significance in the context of a discussion of GINA are

- ACA Section 1001, which creates a new Section 2717 in the Public Health Service Act (PHSA) concerning reporting requirements for group health plans;
- ACA Section 1201, which creates a new Section 2705 in the PHSA prohibiting discrimination on the basis of health status;
- ACA Section 4303, amended by Section 10404 of P.L. 111-152, creates sections in the PHSA, including Section 399MM, which provides for Centers for Disease Control (CDC) technical assistance for employer-based wellness programs; and
- ACA Section 10408, concerning workplace wellness grants.<sup>40</sup>

The new Section 2705 in the PHSA (ACA §1201) prohibits discrimination by group health plans and health insurance issuers on the basis of health status and specifically includes genetic information as a health status related factor. Effective for plan years beginning on or after January 1, 2014, this section generally codifies HIPAA wellness program regulations.<sup>41</sup> Wellness programs that do not require the satisfaction of a standard relating to a health factor and are made available to all similarly situated individuals are not considered discriminatory. If, however, a wellness program conditions receiving a reward (such as a premium rebate) on meeting a health factor-related standard (such as a blood pressure measurement), there are specific requirements, including a cap on the amount of the reward. The reward in these situations must be capped at 30% of the cost of the employee-only coverage under the plan. Under pre-ACA HIPAA regulations, the cap was set at 20%. In addition, under the ACA the Secretaries of HHS, Labor, and Treasury have the discretion to increase this reward to up to 50%.<sup>42</sup> Wellness programs that provide a reward must also

- be reasonably designed to promote health or prevent disease and not be a subterfuge for discriminating based on a health status factor;
- provide eligible individuals the opportunity to qualify for the reward at least once a year;
- be available to all similarly situated individuals; and

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<sup>39</sup> For a more detailed discussion of these provisions, see CRS Report R41278, *Public Health, Workforce, Quality, and Related Provisions in ACA: Summary and Timeline*, coordinated by (name redacted) and (name redacted).

<sup>40</sup> For a discussion of all the ACA provisions relating to prevention and wellness, see CRS Report R41278, *Public Health, Workforce, Quality, and Related Provisions in ACA: Summary and Timeline*, coordinated by (name redacted) and (name redacted), pps. 41-43.

<sup>41</sup> See 29 C.F.R. §2590.702(b)(1)(ii); 45 C.F.R. 146.121(b)(1)(ii); 26 C.F.R. §54.9802-1(b)(1)(ii).

<sup>42</sup> The increase in the amount of the reward available has been lauded by some as encouraging behavioral change that will lead to improved health and lower costs. See Michael O'Donnell, "The Science of Health Promotion," 24 *AMERICAN JOURNAL OF HEALTH PROMOTION* iv (March/April 2010). However, others have argued that tying premium discounts to achieving certain health standards shifts costs to less healthy individuals who tend to be those with lower incomes. See Roni Caryn Rabin, "Could Health Overhaul Incentives Hurt Some?" *THE NEW YORK TIMES* (April 12, 2010); <http://www.nytimes.com/2010/04/13/health/13land.html>.

- disclose in all plan materials the availability of a reasonable alternative standard or the possibility of a waiver.

The requirement that the program be available to similarly situated individuals is further elaborated on in the ACA. The law states that this requirement is not met unless the wellness program allows for “a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard” or for whom it is medically inadvisable to attempt to satisfy the otherwise applicable standard. The ACA allows the plan or issuer, “if reasonable under the circumstances,” to seek verification “such as a statement from an individual’s physician, that a health status factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.”

The other three ACA sections mentioned above, ACA Sections 1001, 4303, and 10408, all encourage the provision of wellness programs.

## **Analysis of Title II of GINA and the ACA**

Both Title II of GINA and the ACA include provisions relating to wellness programs, although the statutes have a different focus. The ACA addresses wellness programs as a means to increase the health of employees and reduce medical costs; Title II of GINA prohibits employment discrimination, generally prohibiting employers from collecting genetic information, and contains broad privacy protections. GINA permits the collection of genetic information for the purpose of wellness programs and contains detailed requirements including, for example, written authorization for the collection of this data. The ACA does not contain similar privacy protections and does not address its relationship with GINA; however, the two statutes do not directly contradict one another. Thus, it could be argued that the disfavored statutory construction approach of repeal by implication would not be appropriate; the two statutes can be read in a complementary manner.<sup>43</sup>

Another rule of statutory construction states that where there is a conflict between the statutes, the most recent statute generally takes precedence.<sup>44</sup> However, it would appear that the provisions of the ACA and GINA are complementary, not contradictory. Like the previous analysis, the ACA and Title II of GINA could be read together in such a way as to give effect to both. Although the ACA does not contain the specific detailed privacy provisions regarding wellness programs contained in GINA, it could be argued that GINA’s provisions supplement the ACA’s nondiscrimination requirements. This argument is further supported by the fact that the nondiscrimination requirements were in the pre-ACA version of HIPAA and the HIPAA regulations contained similar, but not identical, requirements relating to wellness programs. It could even be contended that reading the provisions together would advance the ACA goal of prohibiting discrimination against individuals based on health status, because privacy protections regarding genetic information would decrease the likelihood of discrimination. Thus, it would

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<sup>43</sup> See 1A SUTHERLAND, STATUTES AND STATUTORY CONSTRUCTION §22:34 (Norman J. Singer ed., 7<sup>th</sup> ed. 2009 rev.).

<sup>44</sup> “If two acts of a legislature are applicable to the same subject, their provisions are to be reconciled if this can be done by fair and reasonable intendment, if however, they are repugnant to one another, the last one enacted shall prevail.” Sutherland at §23:18, footnote 8.

appear likely that a court would interpret the wellness provisions of the ACA and Title II of GINA as complementary.

The Preserving Employee Wellness Programs Act (H.R. 1189/S. 620) was introduced on March 2, 2015. As noted, ACA<sup>45</sup> and GINA<sup>46</sup>—as well as the Americans with Disabilities Act (ADA)<sup>47</sup>—may be implicated by any given employer-based wellness program.<sup>48</sup> Generally, S. 620/H.R. 1189 would seek in part to clarify the interaction of these three laws by indicating that those workplace wellness programs that comply with the requirements of the ACA are not in violation of GINA or the ADA. A recent case has highlighted the lack of clarity around the interaction between these three statutes in the context of employer wellness programs. Specifically, on November 6, 2014, a federal district judge in Minnesota declined to enjoin the operation of Honeywell International’s corporate wellness program involving biometric testing in a case brought by the EEOC, claiming violations of both Title II of GINA and the ADA.<sup>49</sup> Although the judge did not express an opinion on either party’s likelihood of success on the merits, she observed that great uncertainty persists in regard to how the ACA, ADA, and other federal statutes such as GINA are intended to interact.<sup>50</sup> On April 20, 2015, the EEOC published a proposed rule to clarify the interaction between the ADA and the ACA employer wellness program provisions;<sup>51</sup> this proposed rule noted that the interaction between GINA and the ACA wellness provisions would be addressed in future rulemaking.<sup>52</sup>

## Conclusion

As noted above, both GINA and the ACA contain provisions affecting certain elements of health insurance, as well as wellness programs. GINA is a civil rights statute and has as its purpose the prohibition of discrimination against individuals on the basis of genetic information. In order to effectuate this prohibition, GINA not only contains certain requirements for health insurance and a general prohibition of employment discrimination provisions, but also has strong privacy protections. On the other hand, the ACA is comprehensive health care legislation that is intended to, among other things, enhance consumer protections in the private health insurance market and expand health coverage. The ACA, the more recent statute, does not specifically amend GINA and also does not reference GINA’s requirements.

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<sup>45</sup> P.L. 111-148, §1201, codified at 42 U.S.C. §300gg-4(j) (amending the Public Health Service Act (PHSA)).

<sup>46</sup> 42 U.S.C. §§2000ff *et seq.*

<sup>47</sup> 42 U.S.C. §§12101 *et seq.*

<sup>48</sup> It may be noted that other federal laws may affect the operation of wellness programs, aside from the Acts discussed in this memorandum. For example, the Employee Retirement Income Security Act (ERISA) imposes certain obligations on employee benefit plan fiduciaries, persons who are generally responsible for the management and operation of employee benefit plans. *See* 29 U.S.C. §1101 *et seq.* In addition, ERISA contains a remedial scheme under which participants and beneficiaries may be able to bring suit for certain ERISA violations. *See* 29 U.S.C. §1132(a). If a wellness program is offered as part of a group health plan under ERISA, then these sections of ERISA may apply to the programs.

<sup>49</sup> EEOC v. Honeywell Int’l, Inc., 2014 WL 5795481 (D. Minn. Nov. 6, 2014).

<sup>50</sup> *Id.* at 5.

<sup>51</sup> 80 *Federal Register* 21659, April 20, 2015.

<sup>52</sup> 80 *Federal Register* 21660, April 20, 2015.

Generally, when interpreting the interactions of two statutes that address similar situations or subject matter, courts will try to read the statutes in such a way as to give effect to the language of both. Further, when Congress enacts legislation to amend an existing statute, courts may attempt to read new provisions together with those that were left unchanged and to interpret the provisions so they do not conflict. A leading treatise on statutory construction also notes that repeal of a prior law by implication is disfavored,<sup>53</sup> and observes that “[t]he point of the rules of interpretation is to give harmonious effect to all acts on a subject where reasonably possible.”<sup>54</sup> However, where a new statute is a comprehensive revision of a subject area there is “a strong implication of a legislative intent to repeal former statutory law.”<sup>55</sup> While the ACA has been described as a comprehensive revision of federal law regarding health care, the act evidences no intent to be the sole regulation of the health care system. Therefore, courts would be more likely to examine the issue through the specific requirements of the statutes of the ACA and GINA and attempt to reconcile these statutes. This more nuanced approach would appear to better reflect and give full effect to the actual language of GINA and the ACA. Ultimately, the precise landscape of these requirements may await final regulations from these agencies and, perhaps, judicial decisions.

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## Acknowledgments

This report was initially co-authored by (name redacted).

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<sup>53</sup> Sutherland at §23:11. *See also*, *Morton v. Mancari*, 417 U.S. 535, 549-551 (1974); *U.S. v. Joya-Martinez*, 947 F.2d 1141 (4<sup>th</sup> Cir. 1991) (“An implied amendment or partial repeal of a statute will not be recognized by the courts, unless it clearly appears the legislature so intended.”). This presumption against implied amendment or repeal can be overridden, but it takes strong evidence of a legislative intent to do so. *Id.*

<sup>54</sup> Sutherland at §23.11. As the Supreme Court has noted, “[i]t is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.... A court must therefore interpret the statute ‘as a symmetrical and coherent regulatory scheme,’ and ‘fit, if possible, all parts into an harmonious whole.’” *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).

<sup>55</sup> Sutherland at §23:13.

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