Employer Wellness Programs and Genetic Information: Frequently Asked Questions

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Contents

Contacts

Since the passage of the Patient Protection and Affordable Care Act of 2010 (ACA, P.L. 111-148, as amended), which encouraged the use of wellness programs, employers have increasingly established employer wellness programs in an effort to support better health among their employees and reduce their own health care costs.[1] Employer wellness programs often focus on improving wellness overall, but they may target a specific disease (e.g., diabetes) or behavior (e.g., smoking), and they may include the provision of health or other services, as well as the collection of health information. These programs often include incentives (that may be either in-kind or financial) for participation, ranging from additional paid time off to reduced insurance premium contributions.[2] A recent comprehensive analysis of employer wellness programs—including their effect on improving health and reducing employers' costs—was carried out by RAND pursuant to a statutory requirement in Section 2705(m) of the Public Health Service Act (PHSA). This analysis and others have found mixed results with respect to the effect of these programs on both health and costs.[3]

Participation in a wellness program almost always involves the provision of medical information—which may include genetic information—by the participant (e.g., the employee, the employee's spouse) to the employer. 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 21st century, was enacted. GINA, P.L. 110-233, prohibits discrimination based on genetic information by health insurers and employers. GINA is divided into two main parts: Title I, which prohibits discrimination based on genetic information by health insurers, 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), through the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as well as the Social Security Act (SSA), to prohibit health insurers from engaging in genetic discrimination. Title II of GINA prohibits discrimination in employment because of 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. The statute also prohibits employers, employment agencies, labor unions, and joint labor-management committees from disclosing genetic information (subject to certain statutory exceptions).[4]

The Equal Employment Opportunity Commission (EEOC) issued regulations implementing GINA Title II that permit employers to request genetic information as part of a wellness program but that prohibit the offering of inducements to secure such information.[5] In other words, the EEOC requires that the provision of genetic information as part of a wellness program be voluntary, as does the statute, and considers the offering of any incentive at all for the provision

[1] See http://www.cdc.gov/workplacehealthpromotion/index.html.

[2] For more information on employer wellness programs in the context of the ACA, see pp. 41-43, CRS Report R41278, *Public Health, Workforce, Quality, and Related Provisions in ACA: Summary and Timeline*, coordinated by (name redac ted) and (name redacted) .

[3] RAND, "Workplace Wellness Programs Study," 2013, http://www.rand.org/pubs/research_reports/RR254.html; RAND, "Workplace Wellness Programs: Services Offered, Participation, and Incentives," 2014, https://www.dol.gov/sites/default/files/ebsa/researchers/analysis/health-and-welfare/WellnessStudyFinal.pdf.

[4] For more information about GINA, see CRS Report RL34584, *The Genetic Information Nondiscrimination Act of 2008 (GINA)*, by (name redacted) and (name redacted)

[5] 75 *Federal Register* 68912 (November 9, 2010).

of genetic information to nullify this voluntariness.[6] As the provision of genetic information as part of a wellness program is statutorily required to be "voluntary," and the statute did not define the term, the meaning of "voluntary" had been a source of ongoing policy discussion—specifically, the issue of at what point incentives for providing genetic information constitute coercion. The EEOC determined that with respect to the provision of genetic information, any incentive at all is coercive.

The EEOC has recently crafted one exception to this statutory and regulatory prohibition on inducements for the provision of genetic information, although it is drafted narrowly and is allowed because the information in question—information about current or past health status of a spouse, provided by the spouse—is, first, health information about the spouse and, second, genetic information about the employee, as per the definition of genetic information and family member in current law. The EEOC provides that inducements for the provision of specified health information by a spouse will follow current law for inducements for the provision of other nongenetic medical information by wellness program participants, rather than be prohibited under current nondiscrimination law applying to the protection of genetic information.

Specifically, in certain cases, an employee's family members—for example, a spouse—may be given the option of participating in a wellness program offered by their family member's employer. The EEOC published a final rule to clarify the interaction between requirements for employer wellness programs as added by the Patient Protection and Affordable Care Act of 2010 (ACA, P.L. 111-148, as amended) and relevant provisions under the Genetic Information Nondiscrimination Act of 2008 (GINA, P.L. 110-233).[7] This final rule addresses the issue of when an employer may lawfully provide incentives for the provision of certain of an employee's spouse's own medical information as a participant in an employer wellness program.[8] The final rule provides that "an employer may offer a limited incentive (in the form of a reward or penalty) to an employee whose spouse receives health or genetic services offered by the employer—including as part of a wellness program—and provides information about his or her current or past health status."[9] This inducement is permitted in this case despite the fact that the information is also technically defined as protected genetic information of the employee under GINA.

Congress has recently introduced legislation that addresses employer wellness programs. H.R. 1313, the Preserving Employee Wellness Programs Act, was introduced on March 2, 2017, and referred to the House Committees on Ways and Means, Education and the Workforce, and Energy and Commerce. The bill would deem those programs that meet specific requirements in the Public Health Service Act (PHSA) to be in compliance with certain nondiscrimination and privacy requirements under GINA and the Americans with Disabilities Act (ADA, P.L. 101-336). In essence, this would appear to have the effect of waiving the voluntariness requirement described above for the provision of genetic information in wellness programs that GINA established and that the EEOC clarified through implementing regulations; in addition, it would also appear to have the effect of waiving privacy protections in GINA related to the employer's treatment of genetic information collected by a wellness program. It would also deem the collection of specified genetic information in the context of a wellness program as being in

[6] 75 *Federal Register* 68935 (November 9, 2010).

[7] 81 *Federal Register* 31143 (May 17, 2016). This final rule followed publication of a proposed rule with a 60-day comment period, which was extended by 30 days to January 28, 2016 (80 *Federal Register* 66853, October 30, 2015).

[8] Ibid.

[9] Equal Employment Opportunity Commission (EEOC), "EEOC's Final Rule on Employer Wellness Programs and the Genetic Information Nondiscrimination Act," https://www.eeoc.gov/laws/regulations/qanda-gina-wellness-final-rule.cfm.

compliance with all of GINA. H.R. 1313 was ordered favorably reported, as amended, by the House Committee on Education and the Workforce on March 8, 2017. Substantively similar, but not identical, bills were introduced in the 114th Congress with the same title (S. 620/H.R. 1189).

This report discusses current law with respect to the collection of genetic information in the context of employer wellness programs. This law is markedly different from that which covers the collection of other nongenetic medical information by wellness programs. It also discusses how current legislative efforts would modify current law with respect to the collection of genetic information in wellness programs if enacted.[10]

The Collection of Genetic Information in Employer Wellness Programs: Current Law

How are the terms "genetic information" and "family member" defined in statute?

Genetic information of an individual is defined in statute as information about (1) an individual's genetic tests, (2) the genetic tests of family members of such individual, and (3) the manifestation of a disease or disorder in family members of such individual.[11] The statute defines "family member" to include relatives out to the fourth degree (e.g., great-grandparent), as well as dependents of the individual.[12] Dependents are persons who are or who become related to an individual through marriage, birth, adoption, or placement for adoption, and includes spouses as well as adopted children, despite the fact that neither of these categories of people would share actual genetic material with the individual in question.[13]

Can an employer request genetic information from an employee as part of a wellness program?

An employer may request—but not require—an employee to provide his or her own genetic information as part of a wellness program. Most if not all employer wellness programs collect medical information from participants, and employers may ask participating employees to answer questions about their own health status and family medical history. Some of this information (e.g., family medical history) falls under the definition of genetic information in Title II of GINA, and

[10] H.R. 1313 would also address harmonization of requirements under the Americans with Disabilities Act (ADA) and the ACA; however, a discussion of that is outside the scope of this report.

[11] 42 U.S.C. 2000ff.

[12] 42 U.S.C. 2000ff.

[13] 75 *Federal Register* 68914 (November 9, 2010). The definition for "dependent" includes relatives that are not blood-related (e.g., spouse, adopted child). This is due to the fact that the definition is partially determined by reference to the use of the term under Section 701(f)(2) of the Employee Retirement Income Security Act of 1974 (ERISA), a statute concerned primarily with employee benefits, including retirement and health benefits. Despite the fact that individuals who are not blood-related do not share any genetic material, the EEOC determined that for purposes of Title II of GINA, dependents include "persons who are or become related to an individual through marriage, birth, adoption, or placement for adoption." The EEOC goes on to say that this decision was made because (1) the reference to ERISA made clear Congress's intent to include dependents by adoption or marriage in the definition, and (2) information about the health of these dependents could be used by an employer to discriminate in health insurance based on higher health costs of the dependent, something that GINA was intended to prohibit.

therefore its acquisition by employers is protected and is protected differently than is employer acquisition of other (nongenetic) medical information.[14]

Must the provision of genetic information by an employee to an employer as part of a wellness program be voluntary?

The provision of genetic information by an employee to an employer as part of a wellness program must be voluntary, an issue that arises especially where participation in wellness programs is incentivized and the provision of medical information is often a requirement of participation. On November 9, 2010, the EEOC issued final regulations for Title II of GINA that clarify that an employee's provision of his or her own genetic information as part of a wellness program must be voluntary, and explains what that means.[15] Specifically, the final rule requires that "the provision of genetic information by the individual is voluntary, meaning the covered entity neither requires the individual to provide genetic information nor penalizes those who choose not to provide it."[16]

How must an employer request genetic information as part of a wellness program?

Although GINA does allow for the voluntary collection of genetic information as part of an employer wellness program, this exception is subject to certain statutory and regulatory requirements.[17] Employers may collect genetic information as part of a wellness program, pursuant to this exception, only if they meet three requirements, as specified by GINA:

1. the employee must provide prior, knowing, voluntary, and written authorization;
2. 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
3. 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.

The regulations implementing GINA require that a health risk assessment (HRA)—the survey often given to participants in wellness programs to collect their health information—must clearly and understandably indicate that the provision of any genetic information asked for on the HRA is not linked to any incentive. Specifically, the final rule explains that an employer "may not offer a financial inducement for individuals to provide genetic information, but may offer inducements for completion of health risk assessments that include questions about family medical history or other genetic information, provided the covered entity makes clear ... that the inducement will be made available whether or not the participant answers questions regarding genetic information."[18]

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[14] For more information, see CRS Report RL34584, *The Genetic Information Nondiscrimination Act of 2008 (GINA)*, by (name redacted) and (name redacted)

[15] 29 CFR Part 1365, "Regulations Under the Genetic Information Nondiscrimination Act of 2008; Final Rule."

[16] 75 *Federal Register* 68935 (November 9, 2010).

[17] 42 U.S.C. 2000ff-1(b)(2).

[18] 75 *Federal Register* 68935 (November 9, 2010). This language was amended by 81 *Federal Register* 31143 (May (continued...)

This language was amended by the EEOC's final rule on employer wellness programs and GINA, to allow an inducement for a spouse's information about his or her own current or past health status; this is discussed further in the section "What does the EEOC's final rule say about a spouse providing information about his or her own current or past health status in exchange for an inducement?"

Does the prohibition on the use of genetic information to discriminate in employment decisions still stand, regardless of how an employer were to acquire such information?

Regardless of how an employer may acquire genetic information (through this exception or any other lawful exception), the employer—including employers, unions, employment agencies, and labor management training programs—is still absolutely prohibited from using the information to discriminate in employment decisions, such as hiring, firing, and promotion.

What are the issues with inducements for a spouse providing his or her own current or past health status?

Often, an employee's family members—for example, a spouse—may be given the option of participating in an employer wellness program. This raises issues with respect to the prohibition on offering an inducement in exchange for the provision of genetic information (addressed in the EEOC's final rule from May of 2016; see "What does the EEOC's final rule say about a spouse providing information about his or her own current or past health status in exchange for an inducement?"). Specifically, the statutory definition of genetic information is such that if a spouse or child provides his or her own current or past health status, that information is not the spouse or child's genetic information under GINA's definition. However, it is still the genetic information of the employee.

For example, if a spouse provides information about his or her current or past health status (e.g., high cholesterol), which is not genetic information about the spouse, it would be considered genetic information about the employee because it is the employee's family history (i.e., family history of high cholesterol) and this information is genetic information under GINA. Therefore, if an employee's spouse provides current health information as part of an employer wellness program, and receives an incentive for doing so, the employee has technically received an incentive for providing genetic information. The end result is that the employer has genetic information about an employee, and the employer provided an incentive to provide that genetic information.

Although this information is legally defined as genetic information, it is not biologically genetic information; that is, nothing about the spouse's current or past health status has any bearing on the genetic makeup—and therefore likelihood of manifesting a disease or condition—of the employee. However, the health status of an employee's spouse could potentially be used by an employer to discriminate against the employee out of concern about higher overall health care costs.

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What does the EEOC's final rule say about a spouse providing information about his or her own current or past health status in exchange for an inducement?

Recently, the EEOC released a final rule addressing the issue of providing incentives for the collection of a spouse's current and past health status as part of a wellness program.[19] The EEOC's final rule allows the employer to incentivize the provision of information about a spouse's own current or past health status (e.g., blood pressure, diabetes), which is also the employee's genetic information, by definition. It does not allow for the employer to incentivize the spouse to provide his or her own genetic information, however (e.g., results of a genetic test, family history).

Does the EEOC's final rule allow an incentive for the collection of an employee's child's current or past health status as part of an employer wellness program?

The EEOC's final rule prohibits the practice of providing an incentive in exchange for an employee's children's current or past health status. The EEOC explained in its proposed rule that it draws the exception (above, for incentives in exchange for the spouse's current or past health status) as narrowly as possible, and therefore does not include an employee's children's information within the exception.[20] In the preamble to the final rule, it states that "the final rule provides that no inducements are permitted in return for information about the manifestation of disease or disorder of an employee's children and makes no distinction between adult and minor children or between biological and adopted children."[21] In addition, in terms of the nature of genetic information, the employee actually shares genetic material with his or her biological children, and so a biological child's health status information would be more informative with respect to an employee than would an employee's spouse's health status information. The preamble to the final rule points out that in the case of an adopted child, the wellness program will not likely know if a child is biological or adopted and that "the information may therefore be used to make predictions about an employee's health."[22]

Would the incentive for a spouse to provide his or her own current and past health status as part of a wellness program be capped?

The incentive to each the spouse and the employee would be capped at 30% of the total annual cost of self-only insurance coverage. EEOC pointed out in its proposed rule that this limit is consistent with limits for inducements established by the ACA.[23]

[19] 81 *Federal Register* 31143 (May 17, 2016).

[20] 80 *Federal Register* 66856 (October 30, 2015).

[21] 81 *Federal Register* 31147 (May 17, 2016).

[22] 81 *Federal Register* 31147 (May 17, 2016).

[23] 80 *Federal Register* 66857 (October 30, 2015).

What requirements must employers follow under Title I of GINA for collecting genetic information in a wellness program that is deemed to be a group health plan?

In certain cases, a wellness program may be deemed to be a group health plan itself. In these cases, it would likely be required to comply with Title I statutory and regulatory requirements. Title I of GINA prohibits discrimination in health insurance based on genetic information. It prohibits group health plans and health insurance issuers from, among other things, requesting, requiring, or purchasing genetic information for underwriting purposes or prior to enrollment.

PHSA Section 2705(d) (as added by Title I of GINA) and related regulations clarify that plans may not collect genetic information for purposes of underwriting, including changes in deductibles or other cost-sharing mechanisms in return for completing a health risk assessment or participating in a wellness program nor with respect to any individual prior to such individual's enrollment under the plan.

Legislation in the 115th Congress

As previously noted, Congress has recently introduced legislation that addresses employer wellness programs. H.R. 1313, the Preserving Employee Wellness Programs Act, was introduced on March 2, 2017, and referred to the House Committees on Ways and Means, Education and the Workforce, and Energy and Commerce. Substantively similar, but not identical, bills were introduced in the 114th Congress with the same title (S. 620/H.R. 1189).

H.R. 1313 would deem those programs that meet specific requirements in the Public Health Service Act (PHSA) to be in compliance with certain nondiscrimination and privacy requirements under GINA and the ADA. In essence, this would have the effect of waiving the voluntariness requirement for the provision of genetic information in wellness programs that GINA established and that the EEOC clarified through implementing regulations; in addition, it would have the effect of waiving privacy protections in GINA related to the employer's treatment of genetic information collected by a wellness program. It would also deem the collection of specified genetic information in the context of a wellness program as being in compliance with all of GINA.

Would the collection of certain health information about family members be allowed?

H.R. 1313 would allow an employer to collect information about both an employee's children's or spouse's manifested diseases or disorders—which would also be genetic information about the employee—as part of an employer wellness program without violating GINA. However, merely collecting any genetic information in the context of a wellness program is not currently a prohibited act under GINA; it is prohibited only if certain requirements are not met, namely (1) the employee must provide prior, knowing, voluntary, and written authorization; (2) only the employee (or family member if the family member is receiving genetic services) 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 (3) any individually identifiable genetic information provided in this context is available only for purposes of such services and shall not be disclosed to the employer except in aggregate terms. In addition, the definition of voluntary is interpreted by the EEOC regulations as the information

being provided without any inducement (with the narrow exception of information about the spouse's own current health information).

This bill would appear to allow for the collection of the specified information about all family members—children and spouses—in exchange for an incentive and without knowing and voluntary written authorization and might allow for the sharing of individual-level information with the employer and with individuals apart from the health care providers involved in the provision of services in the wellness program.

In addition, this bill would stipulate that collection of the specified information about family members would not violate *any* provision of GINA, in either Title I (health insurance) or Title II (employment), as opposed to only specific provisions within GINA.

Would employer compliance with existing statute and regulation in the Public Health Service Act (PHSA Section 2705(j)) ensure compliance with specific nondiscrimination provisions in the ADA and GINA?

H.R. 1313 would require that workplace wellness programs that meet the requirements under PHSA Section 2705(j) and related regulations—as well as those where any reward provided would be less than or equal to the maximum reward amounts provided for in PHSA Section 2705(j)—would be considered to be in compliance with specific provisions of GINA (specifically, the lawful exception to collect genetic information in the context of a wellness program in Title II and the requirements relating to the collection of genetic information for purposes of a group health plan in Title I). This would apply to wellness programs offered in conjunction with an employer-sponsored health plan, to programs not offered in conjunction with an employer-sponsored health plan, and to programs offering more favorable treatment for adverse health factors.

This bill would appear to stipulate that if an employer met the requirements under PHSA Section 2705(j) and related regulations, the employer would be considered in compliance with other additional requirements that may otherwise be imposed under the bill's specified sections of GINA and the ADA. For GINA, this would include the requirements relating to an employee providing knowing, prior, voluntary and written authorization; to the release of individually identifiable genetic information to the employer; and to the restriction of the sharing of the information to only the employee and the relevant health care professional providing health or genetic services. In addition, it would include the EEOC's prohibition on any inducements in exchange for the provision of genetic information in the context of a wellness program (with the narrow exception of the spouse's own current or past health status).

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