Amendments to Regulation Under the Genetic Information Nondiscrimination Act of 2008 (Final Rule)

Clarifies the extent to which an employer may offer an inducement to an employee for the employee’s spouse to provide information about the spouse’s manifestation of disease or disorder as part of a health risk assessment administered in connection with an employer-sponsored wellness program.

Updated last August 16, 2016 for the 5/17/16 draft

WHAT IT DOES

Title II of the Genetic Information Discrimination Act (GINA) prohibits discrimination on the basis of genetic information. The Equal Employment Opportunity Commission (EEOC) established implementing regulations for employers regarding the acquisition of genetic information (Code of Federal Regulations §1635.8). There are six specific exceptions in which the general prohibition against requesting, requiring, or purchasing genetic information does not apply. This updated final rule pertains to the second exception, “Where a covered entity (including private employers and state and local government employers with 15 or more employees, employment agencies, labor unions, joint labor-management training programs, Congress, federal executive branch agencies, and the Executive Office of the President) offers health or genetic services, including such services offered as part of a voluntary wellness program” (1635.8(b)(2)).

The original EEOC rules permitted employers to seek information about manifestation of diseases or disorders in employee’s family members who are receiving health or genetic services from the employer, but did not address whether inducements could be provided in exchange for such information.

This final rule (notified via 81 Federal Register 31143) clarifies “that an employer may, in certain circumstances, offer an employee limited inducements for the employee’s spouse to provide information about the spouse’s manifestation of disease or disorder as part of an HRA [health risk assessment] administered in connection with an employer-sponsored wellness program [ESWP], provided that GINA’s confidentiality requirements are observed and any information obtained is not used to discriminate against an employee.” This updated rule applies to all ESWPs that request genetic information. More specifically, the rule:

- Adds a new section (1635.8(b)(2)(i)(A)), which mandates that employers may request genetic information as part of health or genetic services only when those services are “reasonably designed to promote health or prevent disease.” Programs that would not qualify include those that:
  - Capture data without providing results to employees, unless the collected information is used to design a program that addresses at least a subset of identified conditions;
  - Condition rewards on overly burdensome participation requirements;
  - Exist solely to 1) shift costs from the employer to employee or 2) use data to determine future health costs; or
  - Penalize an employee because a spouse’s manifestation of disease or disorder prevents or inhibits the spouse from participating or from achieving a certain health outcome.
- Adds new language (1635.8(b)(2)(iii) through (v)), which:
  - Clarifies that an employer may offer, as part of an ESWP, a limited inducement (in the form of a reward or penalty) to an employee whose spouse provides information about the spouse’s manifestation of disease or disorder as part of a HRA.
  - Instructs that the inducement may not be offered in return for:
    - The spouse providing his/her own genetic information; or
    - Information about the employee’s children, including 1) manifestation of disease or disorder, and 2) genetic information.
  - Limits the maximum inducement to 30 percent of self-only coverage and provides numerous detailed examples related to plan type.
  - Explains that an employer may not condition participation in an ESWP or otherwise induce an employee, spouse, or
dependent to permit disclosure of genetic information, or waive associated confidentiality rights.

- States that it is unlawful for an employer to deny access to health insurance to an employee and his/her family based on a spouse’s refusal to provide information about his or her manifestation of disease or disorder.
- Eliminates the term “financial” in relationship to inducements, in order to clarify that the term “inducements” includes both financial and in-kind inducements.
- Provides additional examples (1635.8(c)(2)) regarding situations in which an employer is not violating standards for acquiring genetic information.

The rule also adds necessary references to the Health Insurance Portability and Accountability Act (HIPAA) and the Affordable Care Act (ACA).

**RELEVANT SCIENCE**

Genetic information includes information about an individual’s genetic tests and the genetic tests of an individual’s family members, as well as information about the manifestation of a disease or disorder in an individual’s family members (i.e. family medical history). Family medical history is included in the definition of genetic information because it is often used to determine whether someone has an increased risk of getting a disease. A family medical history is a record of health information about a person and his or her close relatives. A complete record includes information from three generations of relatives, including children, brothers and sisters, parents, aunts and uncles, nieces and nephews, grandparents, and cousins. Families have many factors in common, including their genes, environment, and lifestyle. A family medical history can provide information about disease related genes as well as the environment that would affect the expression of the gene. By noticing patterns of disorders among relatives, healthcare professionals can determine whether an individual, other family members, or future generations may be at an increased risk of developing a particular condition. A family medical history can identify people with a higher-than average chance of having common disorders, such as heart disease and high blood pressure. Spouses are excluded from family medical history because their genetics are not closely linked like a family member that comes from the same lineage.

**ENDORSEMENTS & OPPOSITION**

**Endorsements:**

- At present, there have not been publicly reported endorsements to this final rule.

Many organizations endorse the Genetic Information Nondiscrimination Act (GINA). The Institute of Electrical and Electronics Engineers of USA, for example, supported the legislation in a letter: “This bill protects all Americans from the misuse of genetic information in the employment and health insurance decisions. With these protections in place, Americans will be able to use genetics in medicine without fear of misuse of their genetic information.”

**Opposition:**

- At present, there has not been publicly reported opposition to this final rule.

There are several arguments against the Genetic Information Nondiscrimination Act (GINA). For example, a summary by Geneforum stated: “Some people think that the bill is not strong enough” because the proposed legislation “would be limited to cases where an employer intentionally seeks out genetic information about a work and misuses that information.” Tera Eerkes, founder of personal genetic testing company, stated “This measure does not prevent genetic discrimination against people when they are applying for life insurance, or long term care and disability insurance. So, there are still some important gaps in protection and thus there may still be reasons people want to keep their genetic information out of their medical record.”
STATUS

The notice of proposed rulemaking was issued on October 30, 2015. Comments closed on December 29, 2015. The EEOC issued the final rule on May 17, 2016. The effective date of the final rule is July 18, 2016. The applicability date is January 1, 2017.

RELATED POLICIES

There are several other laws related to genetic discrimination. On February 8, 2000, Bill Clinton issued Executive Order 13145, prohibiting discrimination in Federal employment based on genetic information. The Executive Order prohibits federal employers from requesting or requiring any genetic information from their employees, or the use of genetic information in any employment decision. At the time of releasing this executive order, he expressed support for a federal law prohibiting genetic discrimination by private employers or health insurance issuers.

The ACA was passed by Congress and then signed by President Obama on March 23, 2010. On June 28, 2012 the Supreme Court rendered a final decision to uphold the healthcare law. The ACA was enacted to increase the quality and affordability of health insurance, lower the uninsured rate by expanding public and private insurance coverage, and reduce the costs of healthcare for individuals and the government. A major provision of the Act is to establish “guaranteed issue,” meaning issuers offering insurance in either the group or individual market must provide coverage for all individuals who request it. The law therefore prohibits issuers of health insurance from discriminating against patients with genetic diseases by refusing coverage because of “pre-existing conditions.” ACA further provides additional protections for patients with genetic diseases by establishing that certain health insurance issuers may only vary premiums based on a few specified factors such as age or geographic area, thereby prohibiting the adjustment of premiums because of medical conditions such as genetic diseases.

POLICY HISTORY

GINA was passed in the House and Senate and was signed by the President on May 21, 2008. This public law seeks to prevent employment and health insurance discrimination based on genetic information. Title II of GINA specifically describes that it is illegal to discriminate against employees or applicants because of genetic information. It prohibits the use of genetic information in making employment decisions, restricts employers and other entities covered by Title II, including employment agencies, labor organizations and joint labor-management training and apprenticeship programs, from requesting, requiring or purchasing genetic information, and strictly limits the disclosure of genetic information.

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