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Advocacy: the voice of small business in government

April 24, 2009

VIA ELECTRONIC SUBMISSION

The Honorable Stuart J. Ishimaru
Acting Chairman
Equal Employment Opportunity Commission
131 M Street, NE
Washington, DC 20507

Stephen Llewellyn
Executive Officer, Executive Secretariat
Equal Employment Opportunity Commission
131 M Street, NE, Suite 6NE03F
Washington, DC 20507
Electronic Address: http://www.regulations.gov (Docket ID: EEOC-2009-0008; RIN 3046-AA84)

Re: *Regulations under the Genetic Information Nondiscrimination Act of 2008; Notice of Proposed Rulemaking,* 74 *Fed. Reg.* 9056 (March 2, 2009).

Dear Acting Chairman Ishimaru and Mr. Llewellyn:

The Office of Advocacy (Advocacy) of the U.S. Small Business Administration (SBA) is pleased to submit these comments to the U.S. Equal Employment Opportunity Commission (EEOC) regarding its proposed rule[1] that would implement Title II of the Genetic Information Nondiscrimination Act of 2008 (GINA).[2] The proposed rule prohibits the use of genetic information to discriminate in employment, and regulates how employers may use and store genetic information.[3]

Advocacy supports the EEOC's efforts to explain how Title II of GINA will be enforced, but recommends that the EEOC clarify certain provisions highlighted in this comment letter. Most small businesses do not have human resources staff, and it is often the principals of a company that have to implement workplace regulations and make employment decisions. Advocacy recommends that the EEOC develop a small business compliance guide that would provide practical examples of definitions, prohibited conduct, employer best practices and the interaction of this rule with other workplace regulations.

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1 *Regulations under the Genetic Information Nondiscrimination Act of 2008, Notice of Proposed Rulemaking*, 74 *Fed. Reg.* 9056 (March 2, 2009).
2 Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-223, 122 Stat. 881 (2008).
3 74 *Fed. Reg.* at 9056.

The Office of Advocacy

Advocacy was established pursuant to Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within SBA, so the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),[4] as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[5] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small business and to consider less burdensome alternatives.

Background

Congress enacted GINA in response to the developments in the field of genetics, which give rise to the potential misuse of genetic information.[6] GINA prohibits discrimination by health insurers (Title I) and employers (Title II) based on genetic information.[7]

Title II prohibits covered entities from using genetic information to make employment decisions such as hiring, firing and compensation.[8] Title II also restricts the deliberate acquisition of genetic information by employers and requires that covered entities keep genetic information confidential. These prohibitions are subject to limited exceptions. Employers that violate GINA could be liable; damages are limited by the statute to no more than $300,000.[9] Title II of GINA applies to employers with 15 or more employees; and the definition of employees includes current employees, former employees and applicants.[10] Title II of GINA becomes effective on November 21, 2009.

Advocacy Recommendations and Comments on the Proposed Rule

1) EEOC Should Provide Guidance on GINA Definitions

Genetic Information (Section 1635.3c)

The GINA regulations were created to protect against discrimination based on "genetic information," defined as: 1) an individual's genetic tests, 2) the genetic tests of family members and 3) the manifestation of a disease or disorder in family members (also known as family medical history).[11] Genetic information can predict the likelihood that an

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4 5 U.S.C. § 601 et seq.

5 *Small Business Regulatory Enforcement Fairness Act of 1996*, Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et seq.) (*SBREFA*).

6 *Supra* note 2.

7 74 *Fed. Reg.* at 9056.

8 *Id.* Covered entities include employers (private sector, state and local government, Congressional employers, executive branch, federal/civil service), as well as employment agencies, labor organizations, and joint labor-management training and apprenticeship programs.

9 74 *Fed. Reg.* at 9056 . The remedies under GINA model the remedies under Title VII of the Civil Rights Act of 1964, and this includes injunctive relief, and punitive and compensatory damages (up to $300,000). *See* 42 U.S.C. 1983.

10 *Id.*

11 74 *Fed. Reg.* at 9057.

individual will get a disease. For example, a genetic test[12] can determine whether an individual or a member of their family carries the genetic variant evidencing a predisposition to breast cancer.[13] GINA prohibits discrimination based on the manifestation (signs or symptoms) of a disease in family members, just as the Americans with Disabilities Act prohibits discrimination based on the manifestation of a disability or disease in an employee.

Small business representatives have voiced concern that the definition of "genetic information" may complicate an employer's ability to comply with GINA because distinguishing between genetic and other medical information can be difficult to apply in practice. For example, a person with physical symptoms of breast cancer might take a genetic test to confirm these symptoms, and might therefore be covered by both GINA and the ADA. A law review article posed the example of a person with the non-genetic condition of AIDS taking genetic tests to track the progression of this illness, and stated that this person might also be covered by both GINA and the ADA.[14] The EEOC should address whether an employer can be found liable under both statutes, and explain how an employer can tailor a request for medical information to avoid receiving genetic information in these cases. Further, the EEOC should be more specific in determining how an employer would comply with the confidentiality and disclosure restrictions of GINA when the genetic tests and medical information about the presence of a disease are intertwined.

Manifestation (Section 1635g)

Small business representatives also seek clarification of the definition of "manifestation," because GINA covers the manifestation of a disease in family members but not in the employee.[15] "Manifestation," is defined as, "a disease, disorder or pathological condition, that an individual has been or could reasonably be diagnosed with…by a health care professional with appropriate training in the field of medicine involved." However, the definition also states that "a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information or on the results of one or more genetic tests."[16] It is likely that many medical diagnoses are based upon family medical history of illnesses (such as Huntington's disease or Tay-Sachs disease), and therefore a disease itself may be covered under GINA.

Small business representatives have recommended that the EEOC create a user-friendly small business compliance guide that would provide practical examples of these terms and others. This guide should distinguish the technical medical meaning of these terms from their ordinary or plain meaning.

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12 *Id.*

13 *Id.* at 9059.

14 Daniel Schlein, *New Frontiers for Genetic Privacy Law: The Genetic Information Nondiscrimination Act of 2008,* 19 Geo. Mason U. Civ. Rts. L.J. 311, 364.

15 74 *Fed. Reg.* at 9068.

16 *Id*.

2) EEOC Should Clarify Prohibition Against Acquisition of Genetic Information

Acquisition Prohibition (Section 1635.8)

GINA prohibits an employer from acquiring the genetic information of an applicant or an employee, and this includes requesting, requiring or purchasing this information. However, the proposed rule contains exceptions for the lawful acquisition of genetic information.[17] Advocacy recommends that the EEOC clarify the extent of this prohibition and the scope of the exceptions to this rule listed below.

Inadvertent Requests for Information (Section 1635.8-1)

The general prohibition against acquiring genetic information does not apply to situations where an employer inadvertently requests or receives information, either through casual conversations at the "water cooler"[18] or through materials in support of an employee's request for leave or a reasonable accommodation for a disability under the ADA.

The proposed rule states that requests for documentation for leave or for an accommodation under the ADA are considered inadvertent "as long as the request for documentation was lawful, and was not overly broad."[19] The rule notes that an employer best practice may be to "specifically indicate on a questionnaire [to health care professionals]…that family medical history or other genetic information should not be provided."[20] Many small businesses have an informal leave or ADA policy, where employees bring a physician's note to confirm an illness or need for a reasonable accommodation. Advocacy believes that the receipt of genetic information in these types of informal documents should be covered under this exception.

Family and Medical Leave Act (Section 1638.8-2)

GINA allows employers to acquire genetic information under the Family and Medical Leave Act (FMLA) or similar state and local laws, because employees requesting leave for a family member's serious health condition is likely to provide family medical history.[21] Since FMLA only covers businesses with 50 or more employees, small business representatives recommend that the EEOC clarify that this exception applies to other types of leave taken or requested at firms not covered by the FMLA.

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17 *Id.* The six exceptions for the lawful acquisition of genetic information are: 1) where the employer inadvertently requests information; 2) as part of an employer-sponsored health or genetic service; 3) pursuant to the Family and Medical Leave Act of 1993 (FMLA); 4) through documents that are commercially and publicly available; 5) due to genetic monitoring for toxic substances; and 6) for DNA analysis for law enforcement and forensic purposes.

18 *Id.* Water cooler conversations refer to situations where a supervisor might overhear a conversation about genetic information; gets the information from a third party source; or in response to general inquiry by the employer.

19 74 *Fed. Reg.* at 9062.

20 *Id.*

21 *Id.*

Commercially and Publicly Available Information (Section 1638.8-4)

GINA also provides an exception for the review or purchase of publicly available materials that may include a family medical history, such as newspapers, magazines, periodicals, books and the Internet.[22] Advocacy also recommends that personal Web sites, blogs and social networking sites should be included in this exception, because they are so widely utilized by the public.

3) EEOC Should Clarify the Confidentiality and Disclosure Requirements

Confidentiality Requirements (Section 1635.9)

Under GINA, an employer that inadvertently possesses genetic information in writing about an employee must keep this information confidential and maintain this information in medical files (it can be the same files as the ADA medical files) separate from personnel files. Disclosure of genetic information is permitted in limited circumstances.[23] Advocacy recommends that the EEOC provide guidance for how employers must process existing non-medical personnel files and subsequent disclosures of genetic information.

Existing Non-Medical Personnel Files

Small business stakeholders are concerned that GINA does not address whether the disclosure requirements apply retroactively to older files, such as existing non-medical personnel files that may contain family medical history data. For example, the personnel file of an employee who takes bereavement leave to attend the funeral of a close relative may contain a copy of the death certificate in order to be paid for bereavement time.[24] It is unclear whether an employer is required to review non-medical personnel files (such as performance reviews, written reprimands and file memos) and purge all information that could be construed as genetic information. If the EEOC does require that employers review and segregate the personnel files of their former, current and potential employees for this information, then this would constitute a large regulatory burden that must be estimated for purposes of the Regulatory Flexibility Act and the Paperwork Reduction Act.

Subsequent Disclosures

GINA permits limited disclosures such as those pursuant to a court order specifically asking for genetic information or in response to FMLA requests.[25] However, GINA does not specify the required procedures an employer must take in response to a regular subpoena or another request for a personnel or medical file. The rule does not address

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[22] 74 Fed. Reg. at 9063.

[23] *Id.* Disclosure is permitted 1) to the employee or family member upon written request; 2) to an occupational or other health researcher in compliance with OSHA regulations; 3) in response to an order of a court (if the court order expressly requests this information; 4) to government officials investigating compliance with GINA; to comply with provisions of the Family and Medical Leave Act (FMLA) or similar leave laws; 5) to public health agency with regards to particular contagious diseases; consistent with HIPAA Privacy Regulations.

[24] Patricia Alten, *GINA: A Genetic Information Nondiscrimination Solution in Search of a Problem*, 61 Fla. L. R. 379, 391.

[25] 74 *Fed. Reg.* at 9064.

whether an employer is required to redact the genetic information for this subsequent disclosure of genetic information.

4) The EEOC Should Clarify the Interaction of Local, State and Federal Workplace Laws with GINA

Small businesses comply with a myriad of local, state and federal workplace laws that may conflict with GINA, and the EEOC must provide guidance that explains how these requirements differ and interact with each other.

State and Local Laws (Section 1635.11)

The proposed rule states that "GINA makes clear that it does not preempt any other state or local law that provides equal or greater protections than GINA from discrimination and disclosure of genetic information."[26] However, over 40 states have laws addressing genetic discrimination in employment,[27] with different definitions of "genetic information"[28] and varying levels of stringency and penalties. The EEOC should keep an updated list of state and local laws that prohibit genetic discrimination on its website, and catalog which state and local laws are actually preempted by GINA.

Federal Laws (Section 1635.11)

Employers currently comply with many federal workplace discrimination, health and privacy statutes, such as ADA, FMLA, Title VII of the Civil Rights Act of 1964 and the Health Insurance Portability and Accountability Act (HIPAA). Advocacy recommends that the EEOC provide practical guidance, examples and best practices on the difference between these statutes (e.g., coverage, requirements, and prohibitions), how the GINA regulations change these current requirements and the general interaction of these rules with GINA. For example, it would be useful if the EEOC could explain how GINA changes the information that employers can acquire or disclose under these federal laws.

Title I and Title II Firewall (Section 1635.11c)

The proposed rule creates a "firewall" between Title I and Title II actions, preventing "double liability." The firewall seeks to ensure that causes of action for employment discrimination are addressed under Title II; and health plan or issuer discrimination are addressed through Title I.[29] In EEOC testimony, one individual stated that this distinction is often blurred, and the reality is "…in smaller companies, the same person controls HR functions such as hiring and firing, ADA or FMLA claims that may reveal medical and genetic information and the administration of health care benefits."[30] Advocacy recommends that the EEOC clarify how this firewall will work in practice, particularly in small businesses.

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[26] *Id.*
[27] *Id.*
[28] Schlein, *supra* at 347.
[29] 74 *Fed. Reg.* at 9065.
[30] *EEOC Meeting on NPRM of Title II of the Genetic Information Non-Discrimination Act of* 2008, EEOC (Feb. 25, 2009) (statement of Susannah Baruch, J.D., Law and Policy Director, Genetics and Public Policy Center, Johns Hopkins University).

Conclusions

Advocacy applauds the EEOC's efforts to reach out to small businesses to explain the proposal, answer questions and listen to the concerns of small businesses. Advocacy is pleased to forward the comments and concerns of small businesses on this issue, and is willing to assist the EEOC in preparing a small business compliance guide based on public comments and the recommendations in this letter. Please feel free to contact me or Janis Reyes at (202) 205-6533 (Janis.Reyes@sba.gov) if you have any questions or require additional information.

Sincerely,

/s/

Shawne McGibbon
Acting Chief Counsel for Advocacy

/s/

Janis C. Reyes
Assistant Chief Counsel

cc: Kevin Neyland, Acting Administrator, OIRA, OMB