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CLIENT BULLETIN

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GINA: It's More Than Just a Pretty Name

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The employment-related provisions (Title II) of the Genetic Information Non-Discrimination Act of 2008 took effect November 21, 2009. Although the Equal Employment Opportunity Commission, which enforces the GINA, issued proposed regulations in March 2009, the **final regulations** were issued only last week. They will take effect January 10, 2011.

The GINA appears eminently reasonable on its face, but it is riddled with traps and technicalities that could create problems for inattentive employers.

In general, "GINA prohibits use of genetic information in employment decisionmaking, restricts acquisition of genetic information, requires that genetic information be maintained as a confidential medical record, and places strict limits on disclosure of genetic information." Although this sounds unremarkable, an individual's family history is considered "genetic information." Thus, an essential part of most medical examinations is generally off-limits.

GENERAL REQUIREMENTS

Employers will generally be prohibited from requesting information (directly or indirectly) about employees' family histories. This is the case even with otherwise-lawful post-offer medical examinations, fitness for duty examinations, and requests for medical information in connection with a request for reasonable accommodation under the ADA. There are two exceptions: (1) where another federal law *requires* that such information be obtained; and (2) where the employer requests the information in connection with health or genetic services offered by the employer, including voluntary wellness programs (these exceptions are discussed in more detail below).

This restriction of "family history" information even in connection with lawful medical examinations and assessments means that, unless the medical examination falls within one of the two exceptions, employers should delete questions about family history from any forms they or their outside medical care providers use in conducting these examinations. Employers should further instruct their medical providers in writing not to request family history information. *(See "Safe Harbor" language below.)*

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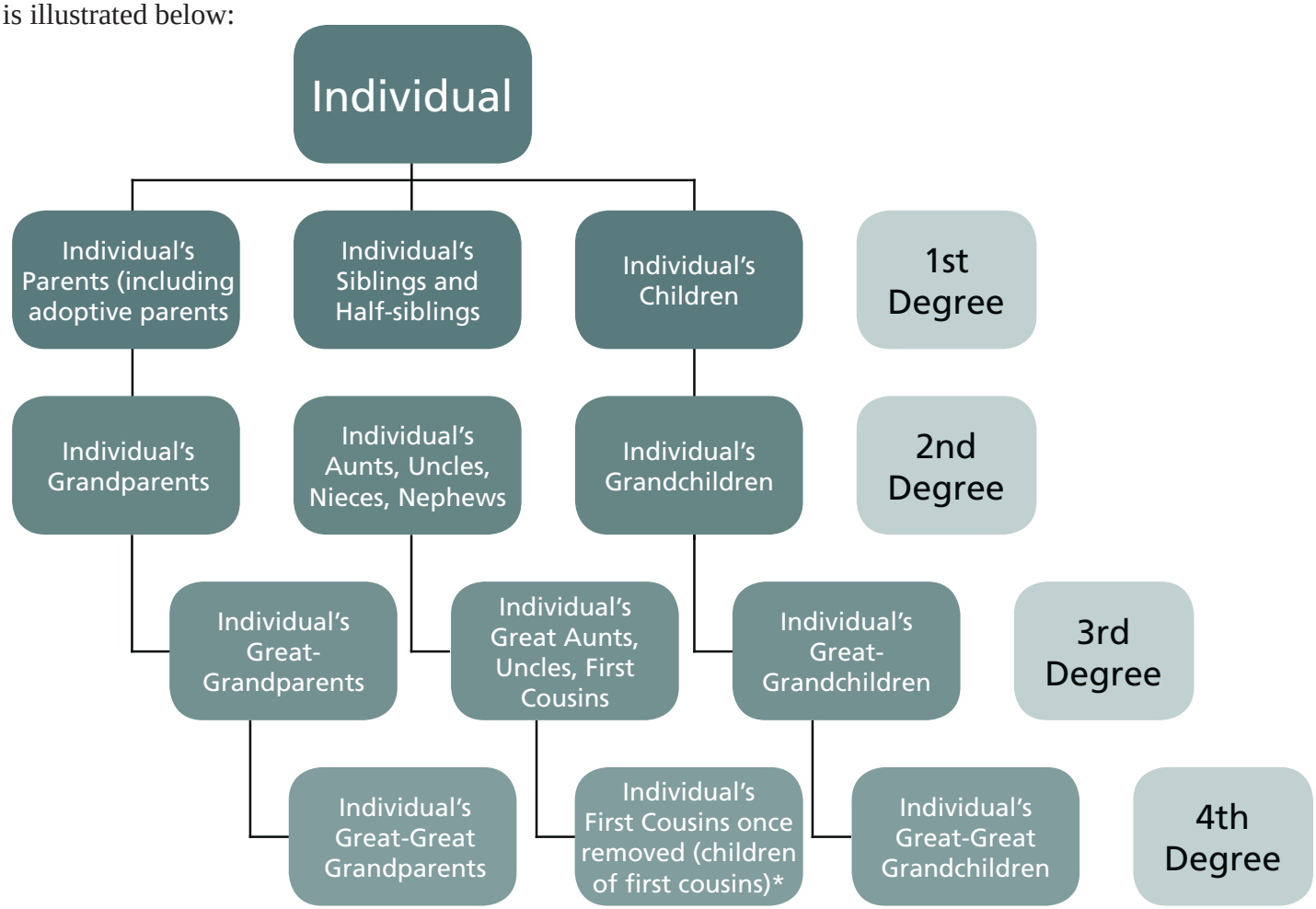
"Family members" include individuals who are "dependents" of the primary individual as a result of "marriage, birth, adoption, or placement for adoption," and first- through fourth-degree blood relatives. The latter category is illustrated below:



** This category also includes great-great uncles, aunts, nieces, and nephews.*

With several exceptions, the GINA prohibits employers from requesting, requiring or purchasing individuals' genetic information. This includes internet searches for genetic information, eavesdropping or searching the individual's personal effects, and asking "about an individual's current health status in a way that is likely to result in a covered entity obtaining genetic information." The regulatory definition of "genetic information" includes not only the individual's genetic testing information but also that of his or her family members as well as the "manifestation of a disease" in family members (*e.g.*, "Has anyone in your family ever had cancer?"). It also includes information about the individual's or family member's request for genetic services, genetic information of a fetus carried by the individual or family member[1], and genetic information of an embryo "legally held by the individual or family member using an assisted reproductive technology" (*e.g.*, *in vitro* fertilization). The statute and regulation specifically exclude sex and age from the definition of "genetic information." The final rule also excludes race and ethnic characteristics if that information is "not derived from a genetic test." A "genetic test" means "an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes." This would include tests designed to assess whether an individual had a predisposition to a medical condition (such as breast cancer) or whether the individual was a "carrier" of a genetic condition, newborn screening analyses, preimplantation diagnosis performed on embryos in connection with in vitro fertil-

[1] Medical dictionaries generally define a human fetus as an unborn child at eight weeks' gestation or later, and before that as an "embryo." Although the regulations do not specifically address embryos *in utero* but only those produced using assisted reproductive technology, presumably the term "fetus" would encompass "naturally conceived" embryos as well.

ization, and DNA testing to determine ancestry or paternity. The regulations specifically exclude drug and alcohol tests, but not tests for *genetic predisposition to alcohol or drug abuse*.

The final regulation includes "safe harbor" language which, if included in a lawful request for medical information that results in disclosure of genetic information, will not result in a violation. This language should be provided with *all* employer requests for medical information, including but not limited to medical certifications for leave under the Family and Medical Leave Act; post-offer, pre-employment medical examinations; workers' compensation requests; and requests for information related to reasonable accommodation under the Americans with Disabilities Act.

SAFE HARBOR LANGUAGE

The Genetic Information Non-Discrimination Act of 2008 (GINA) prohibits employers and other entities covered by GINA Title II from requesting or requiring genetic information of an individual or family member of the individual, except as specifically allowed by this law. To comply with this law, we are asking that you not provide any genetic information when responding to this request for medical information. "Genetic information" as defined by GINA, includes an individual's family medical history, the results of an individual's or family member's genetic tests, the fact that an individual or an individual's family member sought or received genetic services, and genetic information of a fetus carried by an individual or an individual's family member or an embryo lawfully held by an individual or family member receiving assistive reproductive services.

The GINA rules will introduce a level of artificiality to workplace conversations. If a manager or supervisor learns genetic information through a casual conversation, the regulations specify that it is all right to follow up with "How are you?" or "Did they catch it early?" However, it would be unlawful for the manager or supervisor to ask, "Do other members of your family have that condition?" or "Have you been tested for the condition?" Of course, if the manager or supervisor simply cuts off the conversation to avoid violating the GINA, he or she may seem rude or unconcerned. Trying to balance legal requirements with common courtesy, the best course in this situation is probably to follow up with a polite, concerned, "conclusory" statement such as "I'm really sorry," "We'll be thinking about you," or "Please let me know if there is anything we can do." These comments would tend to bring the discussion to a close, and then the manager or supervisor can exit gracefully.

The GINA also prohibits discrimination based on genetic information, and, similar to other federal anti-discrimination laws, applies to employment agencies and labor organizations. It is also unlawful to "limit, segregate, and classify" individuals based on their genetic information. Finally, the GINA also prohibits retaliation against an individual for participating in or engaging in any protected activity under the Act.

As stated above, the GINA has a number of exceptions to its prohibition on seeking genetic information: (1) if the covered entity "inadvertently requests or requires genetic information" regarding the individual or the individual's family member; (2) if the genetic information is acquired in connection with health or genetic services, including a voluntary wellness program; (3) if the employer needs "family medical history" to certify a request for leave under the Family and Medical Leave Act or similar state or local law, provided that the employer requires all employees to provide information about the family members' condition for such leave requests; (4) if the genetic information is disclosed through commercially and publicly available sources; (5) if the genetic information is acquired "for use in the genetic monitoring of the biological effects of toxic substances in the workplace"; or (6) when used for quality control purposes by law enforcement forensic laboratories. Exceptions 1-5 are discussed in more detail below.

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EXCEPTIONS AND SPECIAL RULES

Inadvertent acquisition

Congress has described this as "the water cooler problem." In other words, a member of management overhears casual conversation among employees that reveals some type of genetic information. The statute is aimed only at conversations about the employee's *family members*, but the EEOC is (sensibly) taking the position that inadvertent acquisition about an employee's own genetic information also falls within the exception.

In addition, if the employer receives the information unsolicited – either in conversation; or in response to a lawful request for medical information related to reasonable accommodation or some other lawful request covered by federal, state, or local law (such as workers' compensation information); or in support of a leave request; or in response to a question about an individual's or family member's general health ("How ya' doin'?" or "How's your daughter doin'?"); or in response to a question about the individual's current health – it falls within this exception and does not violate the GINA.

Acquisition through genetic services/wellness program

For this exception to apply, the individual must provide a written authorization in plain language that describes the genetic information to be obtained and the purpose for which it will be used, as well as the restrictions on disclosure of genetic information. Once acquired, the information (if individually identifiable) may be disclosed only to the individual or family member, and the "licensed health care professional or board certified genetic counselor involved in providing such services." The information cannot be disclosed to the covered entity in individually identifiable form but may be disclosed in the aggregate.

Acquisition through FMLA medical certification

This exception does not mean that an employer can request any sort of genetic information to certify an FMLA request. The exception is far more limited than that. What it does mean is that an employer will not be violating the GINA by requesting a medical certification based on the "serious health condition" or "serious injury or illness" of an employee's spouse, parent, child, or (in the case of "serious injury or illness leave") next of kin, so long as it requests medical certifications in all such circumstances. The same rules apply to requests for "family" leave under applicable state or local laws.

Acquisition through commercially and publicly available sources

Although it is not a violation of the GINA for an employer to acquire genetic information through newspapers, magazines, books, television, movies, or the Internet (websites or blogs that do not require permission for access), the employer may not research medical databases or court records to gather genetic information. Even using "lawful" sources is unlawful if the employer deliberately sets out to obtain genetic information (for example, doing a Google search for "Dwight Schrute and sickle cell anemia"). Moreover, social networking platforms that require the permission of the creator for access – including MySpace, Facebook, and the like, are not considered "commercially and publicly available" unless the employer can prove that access is routinely granted to everyone who requests it.

The regulations provide that the GINA prohibitions do not apply to genetic information acquired *outside* the employment context.

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Acquisition through biological monitoring for workplace toxic substance exposure (and other OSHA issues)

Certain Occupational Safety and Health Administration standards require, and other OSHA guidelines recommend, that employers monitor their employees' workplace exposure to particular toxic substances, such as lead or cadmium, through testing of the employee's blood and/or urine. If genetic information is acquired through such testing, then there would be no GINA violation according to this exception.

However, the exception apparently would not apply and it would be a GINA violation if genetic information were acquired as a result of other types of medical examinations required by OSHA for purposes other than monitoring the biological effects of toxic substance exposure. For example, OSHA's Respiratory Protection Standard requires medical evaluation to determine an employee's physical ability to use a negative pressure respirator under the conditions of the particular workplace. Although the medical questionnaire provided by OSHA for this purpose does not specially ask for genetic information, the standard provides that when the employee's questionnaire responses show the need for a follow-up medical examination, that examination may include any medical tests, consultations, or diagnostic procedures that the evaluating physician or other licensed health care professional deems necessary to make a final determination about the employee's ability to wear the respirator. Such tests and consultations could very well involve the health care professional's acquisition of the employee's family medical history, as well as possibly other types of genetic information.

"If an OSHA standard *requires* that the employer (directly or indirectly) obtain family history, then it would not be a violation of the GINA for the employer to do so. . . . However, if – as is more frequently the case – the OSHA standard gives the health care provider *discretion* to determine what type of medical evaluation is appropriate, then arguably it would violate GINA for the health care provider to seek family history information."

As discussed above in general, if an OSHA standard *requires* that the employer (directly or indirectly) obtain family history, then it would not be a violation of the GINA for the employer to do so, provided the employee is given written notice of that genetic monitoring and informed of the results. For example, OSHA's Asbestos Standard requires that employees who are exposed to certain levels of airborne asbestos be provided with medical examinations that *must* include questions about family history. Therefore, it would not be a violation of the GINA for a health care provider to ask about family history while conducting a medical examination under the Asbestos Standard. However, if – as is more frequently the case – the OSHA standard gives the health care provider *discretion* to determine what type of medical evaluation is appropriate, then arguably it would violate the GINA for the health care provider to seek family history information.

Even when there is no OSHA requirement involved, the treating physician in a workers' compensation case may need to acquire the injured or ill employee's family medical history in order to determine to what extent the employee's work or work environment may have caused or contributed to the employee's medical condition, as opposed to the employee's own physical predisposition to develop the condition regardless of the work. For example, an employee's back condition may be solely attributable to non-work-related degenerative disc disease, or hearing loss might be caused by some inherited pathology unrelated to noise exposure. Such determinations are routinely made by physicians to whom employers send their employees for reportedly work-related conditions, and they bear directly on both the employer's workers' compensation liability and the number of cases that must be recorded on the establishment's OSHA 300 Log of work-related injuries and illnesses (information used by OSHA to target inspections). Under the GINA, the employer's physician would be restricted from obtaining all of the information that might be necessary to make these important determinations.

Confidentiality

Any genetic information that is acquired (even lawfully) must be kept confidential as provided in the Americans with Disabilities Act – that is, the information must be stored in a confidential file, separate from any personnel documents. However, the employer may disclose the information to the individual or family member about whom the information pertains; to an occupational or other health researcher conducting research in compliance with 45 C.F.R. Part 46 (dealing with protection of human subjects); in response to an express directive of a court order, with disclosure to the individual to whom the information pertains if the order was obtained without the individual's knowledge; in support of an employee's compliance with medical certification under the FMLA or a state family/medical leave law. In addition, the employer may disclose a manifested disease or disorder to a federal, state, or local public health agency concerning "a contagious disease that presents an imminent hazard of death or life-threatening illness" if it also notifies the individual whose family member is the subject of the disclosure.

And, as always, it is lawful for the employer to disclose genetic information to the "government officials investigating compliance" provided that the information is relevant to the investigation.

Any genetic information that was placed in a personnel file before November 21, 2009 (the effective date of the GINA) may stay there, but the employer may not use or disclose the information. It is doubtful that any employers will have genetic information in personnel files in any event because of the ADA's requirements on confidentiality of medical information.

Interaction of GINA with HIPAA Privacy Rule and wellness programs

The final regulations generally do not apply to or affect "protected health information" subject to the Privacy Rule under the Health Insurance Portability and Accountability Act. The HIPAA Privacy Rule applies only to "covered entities" as specifically defined under HIPAA, and most employers do not meet that definition unless they are health care providers. For employers who are also health care providers, the GINA governs the use of genetic information collected or obtained in the employment context, such as part of a request for leave by an employee. By contrast, if the same employer collects or obtains genetic information in its role as a health care provider, such as while providing medical treatment to the employee in the employee's capacity as a "patient" rather than as an "employee," then the genetic information is subject to the HIPAA Privacy Rule and not the GINA. Therefore, for employers who are also health care providers, the context in which the genetic information is collected or obtained determines whether the GINA or the HIPAA Privacy Rule applies.

The GINA, however, does expand the non-discrimination provisions of HIPAA. The GINA prevents a group health plan or health insurance issuer from imposing a preexisting condition exclusion based solely on genetic information. It also prohibits discrimination based on any health factor, including genetic information, with respect to individual eligibility, benefits, or premiums. Group health plans and health insurance issuers may not use genetic information in determining premiums for an employer or a group of similarly situated individuals.

The GINA also generally prohibits a group health plan from collecting genetic information (including family medical history) before or in connection with enrollment, or for underwriting purposes. However, there is an important exception that applies to voluntary wellness programs as part of group health plans. An employer who offers such a program may ask questions related to the genetic background of employees if (1) the employee provides prior voluntary and written authorization to disclose genetic information or family medical background information; (2) the authorization form is written in language which is reasonably likely to be understood by the

employee; (3) the form describes the type of genetic information that will be obtained and the general purposes for which it will be used; and (4) the form describes the restrictions on use of the information. The authorization form may be electronic.

An employer may not offer a special inducement for employees to provide genetic information.

Many employers ask employees to complete a Health Risk Assessment form before enrolling in a wellness program. In the past, HRA forms have commonly included questions which relate to the genetic or family medical background of the employee. Under the final GINA regulations, HRA forms may continue to include such questions, but only if (1) the questions seeking genetic information or family medical background are separately and specifically identified on all forms; (2) employees are notified, in language which is reasonably likely to be understood, that responses to those questions are completely voluntary; and (3) employees who decline to answer those questions are not penalized in any way (for example, by exclusion from the wellness program or a reduction in the financial incentive for participation). If an employer meets all three conditions, genetic background questions on HRA forms will not violate the GINA or the final regulations.

Finally, in addition to wellness programs, many employers offer disease management or healthy lifestyle programs which include a financial incentive for employees to meet specific health goals (for example, by achieving a certain weight, cholesterol level, or blood pressure). The same rules described above also apply to enrollment questions for disease management and healthy lifestyle programs. The final regulations specifically require that any financial incentive to participate in a disease management or healthy lifestyle program must be equally available to employees with current health conditions and/or whose lifestyle choices put them at risk of acquiring a condition.

Thus, under the GINA, employers may continue to offer rewards under wellness, disease management, and healthy lifestyle programs and, within the limitations described above, collect genetic information, including family medical history information collected as part of a Health Risk Assessment. However, employers will need to carefully review the questions included on all HRA and related forms to ensure that they are compliant with the GINA's restrictions.

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