



**BlueCross BlueShield  
Association**

An Association of Independent  
Blue Cross and Blue Shield Plans

December 9, 2008

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Daniel J. Maguire  
Director  
Office of Health Plan Standards and Compliance Assistance  
Employee Benefits Security Administration  
Room N-5653  
U.S. Department of Labor  
200 Constitution Avenue, N.W.  
Washington, DC 20210

**Attention:** GINA Request for Information Comments

**By E-mail:** E-OHPSCA.EBSA@dol.gov

**RE:** Request for Information Regarding Sections 101 through 104 of the Genetic Information Nondiscrimination Act of 2008, 73 *Fed. Reg.* 60208 (October 10, 2008)

Dear Mr. Maguire:

The Blue Cross and Blue Shield Association (BCBSA), which represents the 39 independent, community-based and locally operated Blue Cross and Blue Shield Plans (Plans), is pleased to submit these comments in response to your request for public comment on Sections 101 through 104 of the Genetic Information Nondiscrimination Act of 2008 (GINA). BCBS Plans have served their communities for more than 75 years, and currently collectively provide healthcare coverage for more than 102 million people or one-in-three Americans. Plans provide coverage in all 50 states, the District of Columbia, and Puerto Rico and in all markets, including the individual, small group, large employer, and national account markets.

Blue Cross and Blue Shield Plans do not deny coverage to members based on their confidential genetic profiles, and support protections on the use of genetic data. BCBSA also supports GINA because it encourages patients to obtain appropriate genetic testing to take advantage of prevention and effective treatment – rather than delay potentially life-saving care.

## **Comments Regarding Economic Analysis, Paperwork Reduction Act, and Regulatory Flexibility Act**

*What policies, procedures, or practices of group health plans and health insurance issuers may be impacted by regulations under GINA?*

A few Plans may still ask for family history as part of the underwriting process. GINA prohibits this practice.

*What direct or indirect costs would result?*

Plans that need to change their application forms will incur expenses for revising these forms and providing guidance to their personnel for use of the revised forms.

*What direct or indirect benefits would result?*

Individuals who may have a potentially adverse family history would be accepted for coverage.

*Which stakeholders will be impacted by such benefits and costs?*

Insurers and producers would face higher initial costs to change forms and learn the use of new forms.

*Are there unique costs and benefits for small employers or small plans?*

See answer to next question.

*What special consideration, if any, is needed for small employers or small plans?*

Small employers and small benefit plans face special challenges in complying with legislation. Any burdensome, detailed reporting or other compliance requirements would be especially onerous for them due to their smaller size and limited resources available to them.

## **Comments Regarding Regulatory Guidance**

- 1. To what extent do group health plans and health insurance issuers currently use genetic information, such as family medical history, and for what purposes? For example, is genetic information currently used for group rating purposes, or for purposes of a wellness program that otherwise complies with HIPAA's nondiscrimination requirements?*

**Genetic Information is Not Considered** – In general, Blue Cross and Blue Shield Plans do not use genetic information for “underwriting purposes” as

that term is defined in GINA, that is, eligibility for coverage; premiums; preexisting condition exclusions; and creation, renewal, or replacement of coverage (see 29 U.S.C. § 1191b(d)(9); 42 U.S.C. 300gg-91(d)(19); 26 U.S.C. § 9832(d)(10); 42 U.S.C. § 1395ss(x)(3)(E)).

**GINA Permits Use of Information on Manifested Diseases/Disorders –**

GINA distinguishes between the prohibited activity of collecting and using genetic information for underwriting purposes and the permissible activity of using manifested diseases or disorders to establish premiums for an employer, or to establish premiums, eligibility, or preexisting conditions for an insured in the individual market. The agencies should use caution to assure that this distinction is clear in regulations. See 29 U.S.C. § 1182(b)(3)(B); 42 U.S.C. 300gg-91(b)(3)(B); 42 U.S.C. § 300gg-53(a)(2), (b)(2); 26 U.S.C. § 9832(b)(3)(B); 42 U.S.C. § 1395ss(s)(2)(F).

**GINA’s Restrictions are Limited to Underwriting –** Insurers are prohibited from using genetic information to adjust premiums or establish eligibility. This prohibition does not apply to wellness programs. See 29 U.S.C. § 1182(b)(3)(B); 42 U.S.C. 300gg-1(b)(3)(B); 42 U.S.C. § 300gg-53(a)(2), (b)(2); 26 U.S.C. § 9832(b)(3)(B); 42 U.S.C. § 1395ss(s)(2)(F).

Further, the prohibitions on using, requesting, or requiring genetic testing do not apply when health care professionals providing health care services to individuals request that those individuals undergo genetic tests. See 29 U.S.C. § 1182(c)(2); 42 U.S.C. 300gg-1(c)(2); 42 U.S.C. § 300gg-53(a)(2), (b)(2); 26 U.S.C. § 9832(c)(2); 42 U.S.C. § 1395ss(x)(1)(B).

2. *How do plans and issuers currently obtain genetic information (for example, through health risk assessments, the Medical Information Bureau, or other entities under common control)?*

**Plans Do Not Seek Genetic Information for Underwriting –** Blue Cross and Blue Shield Plans conduct underwriting based on claims history, case management, and drug profiles. These records all refer to manifested diseases or disorders and genetic information is not sought in this process. Blue Cross and Blue Shield Plans do not currently use the MIB to obtain information for underwriting.

Health risk assessments are used as part of wellness programs and may request family histories that fall within the definition of “genetic information.” This information is not used for underwriting purposes, but is instead used for health promotion and disease management.

3. *Under what circumstances do plans or issuers currently request or require an individual to take a genetic test?*

**Genetic Testing Not Requested or Required for Underwriting – Blue Cross and Blue Shield Plans** do not request or require genetic tests for underwriting purposes.

**Genetic Testing May be Requested by Health Care Professionals – GINA** specifically permits health care professionals providing health care services to an individual to request an individual to take a genetic test. See 29 U.S.C. § 1182(c)(2); 42 U.S.C. 300gg-1(c)(2); 42 U.S.C. § 300gg-53(a)(2), (b)(2); 26 U.S.C. § 9832(c)(2); 42 U.S.C. § 1395ss(x)(1)(B).

A report on the Senate version of GINA (S. 358) noted that the Senate version specifically allowed health care professionals to notify insureds about genetic testing to participants in a wellness program:

...[T]he committee is also aware that some health plans go beyond the insurance function and engage in wellness and disease management programs; and the committee does not wish to discourage such efforts. Thus, section 101(b) makes it clear that this legislation does not limit the authority of a health care professional who is employed by or affiliated with the group health plan or health insurance issuer who is providing health care services to the enrolled individual as part of a wellness program from notifying such individual about the availability of a genetic test or providing information about the genetic test.

The term “wellness program” is defined by regulations promulgating ERISA’s nondiscrimination provisions under section 702. In summary, these regulations define a “wellness program” as one that does more than simply charging differential premiums based on health risk factors. For instance, a wellness program might include a rebate for not smoking, but it would also have to offer a smoking cessation program. The committee believes that the concept of a wellness program is important in the context of genetic discrimination to ensure that a health plan does not use a wellness program as a subterfuge to discriminate in insurance premiums based on genetic information.

Sen. Rep. No. 110-48, at 19-20 (2007).

4. *Under what circumstances do plans or issuers currently ask for the results of a genetic test in order to make a determination regarding payment of benefits? What is the minimum amount of information necessary for a plan or issuer to make a determination under such circumstances?*

**Genetic Test Results Are Obtained When Needed for Claims**

**Determinations** – Blue Cross and Blue Shield Plans typically provide coverage for medically necessary treatment and for preventive medical tests performed periodically. Sometimes questions arise as to whether treatment is medically necessary or if more frequent preventive testing is appropriate, and genetic tests help insurers resolve these questions. Here is an example from Sen. Rep. No. 110-48, at 21 (2007):

The Consolidated Mutual Insurance Company covers one colonoscopy every 10 years for beneficiaries above the age of 50. However, the plan covers the cost of an annual colonoscopy for beneficiaries of any age who have a mutation in one of several genes associated with elevated risk of hereditary nonpolyposis colorectal cancer (HNPCC). Mr. Monroe had a colonoscopy when he turned 50, the cost of which Consolidated Mutual covered. However, the following year, Mr. Monroe had a second colonoscopy for which he also sought reimbursement from Consolidated Mutual. Mr. Monroe claimed that Consolidated Mutual should cover the second colonoscopy on the grounds that a genetic test detected that he carries a mutation in one of the genes associated with elevated risk of HNPCC. Nothing in subsection (c)(1) [*i.e.*, the prohibition on requesting/requiring genetic testing] prohibits Consolidated Mutual from requiring that Mr. Monroe provide evidence to show that he indeed did undergo the relevant genetic test, and that the results fell within the scope of conditions under which Consolidated Mutual's policy rules provide coverage for colonoscopies performed more frequently than once per decade.

Another example would be where benefits cover genetic tests such as the BRCA test related to breast cancer. Blue Cross and Blue Shield Plans establish criteria to determine when the test is covered. To determine if criteria supporting coverage are met, documentation and family history are needed.

**Minimum Information Necessary will be on a Case-by-Case Basis** – The amount of information necessary will vary depending on the circumstances. In the examples given above, it is necessary to know the results of the genetic test to confirm that the individual's genetic makeup justifies payment for additional expenses. However, if the issue is whether an insurer should pay the expenses for a genetic test, the insurer may need only the confirmation that the test was, in fact, performed, not the results of the test.

5. *What types of research do plans or issuers currently conduct or support using genetic tests?*

**GINA's Research Exception Applies Only to Clinical Research** – GINA's research exception is written so that it applies to requests to undergo genetic testing for clinical research. Blue Cross and Blue Shield Plans often conduct research using their claims databases that may include the fact that claims were paid for genetic tests or claims were paid for multiple members of the same family. However, Blue Cross and Blue Shield Plans do not consider the results of genetic tests nor do they request individuals to undergo a "genetic test" as that term is defined in GINA. See 29 U.S.C. §§ 1182(c)(4), 1191b(d)(7); 42 U.S.C. §§ 300gg-1(c)(4), 300gg-52(d)(4), 300gg-91(d)(17); 26 U.S.C. §§ 9802(c)(4), 9832(d)(8); 42 U.S.C. § 1395ss(x)(1)(D), (3)(C).

6. *Would a model notice be helpful to facilitate disclosure to plan participants and beneficiaries regarding a plan's or issuer's use of the research exception? In this regard, what information would be most helpful to participants and beneficiaries?*

**Notice is Unnecessary for Research Using Claims Databases** – See response to Question 5.

7. *Similarly, would a model form be helpful for reporting to the Departments by a plan or issuer claiming the research exception? In this regard, what information should plans and issuers report?*

**Notice is Unnecessary for Research Using Claims Databases** – See response to Question 5.

8. *When might genetic information be collected incidentally?*

Genetic information may be found through all types of health records, so it is difficult for health insurers to guard against incidental collection of genetic information in every possible situation. If genetic information is obtained in any transaction not specifically for the purpose of obtaining genetic information, the genetic information should be considered as obtained incidentally.

Typical situations in which health insurers may acquire genetic information incidentally:

**Volunteered by Individuals** – Individuals making claims or service inquiries may refer voluntarily to health histories, including diseases or disorders of family members, which GINA defines as "genetic information."

**Wellness Programs** – The programs often utilize health risk assessments that request family health histories that fall within the definition of “genetic information.” This information is used for health promotion and disease management, but is not used for underwriting purposes.

**Issuing Quotes for Prospective Group Business** – Employers generally provide claims files from previous insurers in order to obtain new quotes. Embedded in this claim information may be claims filed for genetic tests or claims filed for members of the same family.

**Utilization/Quality Management Functions** – Review of members’ utilization of health care services and the quality of the service they receive may lead to incidental collection of genetic information, for instance, information that a claim for a genetic test was paid.

**Records Obtained Due to Merger, Consolidation, Etc.** – Health insurers may acquire other health insurers or reinsure the risks of other insurers and through that process incidentally obtain genetic information in records transferred in the transaction.

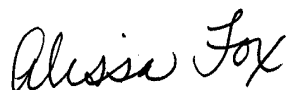
9. *What terms or provisions (such as genetic information, genetic test, genetic services, or underwriting) would require additional clarification to facilitate compliance? What specific clarifications would be helpful?*

**The difference between the terms “collection of information,” “use of information,” and “acquisition of information”** – For example, just because a health plan or insurer acquired genetic information does not mean that the health plan collected it or used it.

**Genetic Information is Protected by HIPAA Privacy Rules** – Health insurers consider genetic information to be protected health information under HIPAA privacy rules and there is no need for additional data protections for this type of data. Indeed, additional requirements may create confusion.

Thank you for the opportunity to comment on these issues. Please contact me if additional information is needed on these comments.

Sincerely,



Alissa Fox  
Senior Vice President